

THE UNITED STATES ARMY MEDICAL DEPARTMENT JOURNAL

PREHOSPITAL COMBAT CASUALTY CARE THE STARTING POINT OF BATTLEFIELD SURVIVAL

April - June 2011

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Perspectives

COMMANDER'S INTRODUCTION

MG David A. Rubenstein

The Marine Corps has a fundamental tenet which is ingrained in every Marine, from the Commandant to the newest boot camp graduate:

The only reason for your existence in the Corps, no matter your job, is that Marine rifleman in the foxhole. Everything you do must ultimately contribute to his effectiveness and survival on the battlefield.

With regard to our ultimate purpose, a similar principle is applicable to most of us in the Army Medical Department. Indeed, the historical foundation for the existence of military medicine is management of trauma injuries incurred by Warfighters in combat. When reduced to its essence, that trauma care starts with the combat medic, who must call upon all of the training, skills, and equipment that we have given him/her to keep wounded Soldiers alive until they are in the hands of our superbly capable surgeons. Those combat medics are the core of prehospital care on the battlefield, that absolutely crucial phase of combat trauma care that can determine the outcome of the casualty's journey through the medical care system. The survival of that combat casualty is the primary reason for our existence, and the combat medic is the starting point to make that happen.

We in the AMEDD live and work in the real world. Every day presents new, "right now" crises and challenges clamoring for our time and attention. In the bedlam of so many complications and diversions, so many requirements pulling from all directions, and so many demands for instant responses, it is sometimes difficult to keep our collective concentration directed towards the ultimate responsibility. COL Lorne Blackbourne, Commander of the US Army Institute of Surgical Research (ISR), and his team have assembled

this very important issue of the *AMEDD Journal* to refocus on prehospital care of combat trauma. Drawing on the considerable resources of the ISR's professional staff and their counterparts in research and the practice of trauma care from across the country, this impressive collection of articles explores a broad spectrum of topics dealing with the current and future states of prehospital combat trauma care. The articles cover the gamut, including research in medications, techniques, and tools; data requirements, management, and value; and the qualifications and training of our frontline medical professionals. Readers may find some of the content a bit controversial, perhaps even provocative, but the Army is a learning organization, and we as leaders and professionals must always recognize facts for what they are, especially when lives may be on the line.

The AMEDD is responsible for many varied disciplines encompassing nearly every aspect of modern medicine. Obviously, all are very important to the health and welfare of our Warfighters. However, when the urgent cry "MEDIC!" rings across the chaos of a battlefield, nothing is more vital at that moment than the capabilities that the AMEDD has given that Soldier and those that will assist in moving the casualty to the next level of care. For that reason, the articles in this issue should be of great interest to the vast majority of AMEDD medical professionals, whether or not you are directly involved in combat casualty care. All military medical professionals should be impressed by the dedication and focus of those continuously involved in working to optimize the odds of survival of our Warriors who go into harm's way, whenever and wherever necessary.

EDITORS' PERSPECTIVE

COL Lorne Blackbourne opens the collection of focus articles with a retrospective look at the evolution of prehospital trauma care since 1831. Interestingly, 1831 is significant to medical science because in that year occurred the first documented use of intravenous fluid. Technological advances in medical science, as well as

throughout almost all aspects of human endeavor, have been breathtaking, and, by and large, greatly beneficial. However, COL Blackbourne presents a comparison of the technology of prehospital battlefield care in 1831 and today, and his conclusions reveal a surprising lack of significant advancement in both sophistication and variety in diagnosis and treatment over the years. His article sets the stage for the articles

that follow, which demonstrate that military medicine in general, and the Army Institute of Surgical Research in particular, has considerable resources dedicated to rectifying this situation as rapidly as possible, working to improve every facet of prehospital battlefield trauma care.

COL Brian Eastridge and his team examined the differences between the advances of military trauma care in the hospital setting and that experienced in the prehospital environment from the perspective of the evidence that drives change and improvement. The Army has implemented sophisticated data collection systems and databases specifically to track injuries and allow thorough analysis of both successes and failures of treatments, including all the factors which can be quantified. Such analyses and implemented protocols, equipment, and supplies have resulted in tremendous advances in acute care management of the combat casualty. Unfortunately, as COL Eastridge et al describe in detail, such necessary data is almost never available from the prehospital care phase of combat trauma care. Without that data, those dedicated to improving the prehospital care capabilities are essentially hunting for solutions armed with suboptimal evidence, when any exists at all. The article describes the military's efforts to address this problem, with the establishment by DoD of the Tactical Combat Casualty Care (TCCC) guidelines with participation of all the services. These guidelines are under constant review and modification based on evidence gathered from numerous sources, as well as unrelenting efforts to gather data from the actual battlefield environment. This is difficult, but the paramount importance of such data cannot be overemphasized.

In the next article, LTC Russ Kotwal and his coauthors describe one early initiative to implement TCCC protocols and procedures, and directly address the lack of prehospital data. The 75th Ranger Regiment developed and implemented a regiment-wide program of training in TCCC basics, especially the recording of casualty data from the first contact with any responder, whether a medic or not. The Regiment created a Soldier's data card specifically to capture the TCCC data, and ensured that command emphasis on its use was constant, including training classes and during field exercises. That data card eventually became the Army's standard TCCC card (DA Form 7656). As the Regiment's collection of data from the TCCC card

improved in quality and quantity, a database for the TCCC data was developed: the prehospital trauma registry. LTC Kotwal et al discuss the evolution of that registry into a web-based tool that has markedly improved the command's ability to devise treatment protocols and procedures based on evidence, one of the essential elements discussed previously as historically unavailable. This article is yet another example of the initiative, skill, and energy of our military medical professionals in pursuing the primary goal, survival of the Warfighter.

It is well documented that hemorrhage has historically been, and remains, the primary cause of death on the battlefield. Further, data from current combat operations indicate that two-thirds of hemorrhage-related deaths in those conflicts have been from noncompressible injuries. As Dr Michael Dubick describes in his excellent article, often there is little the combat medic can do for such casualties beyond infusing fluid to maintain blood pressure until surgical resources can be reached. However, even that capability faces limitations in supply, and certain types of intravenous fluids are not suitable for this application. The article focuses on the current thinking with regard to optimal fluid resuscitation strategies to give the combat medic the best chance to stabilize the combat casualty. The concept of damage control resuscitation has been developed to describe those optimal strategies as battlefield data and attendant research reveal what works, and what does not. Dr Dubick's article details the background, data, practices, and research in progress within the damage control resuscitation concept, the majority of which is the direct result of work at the Army Institute of Surgical Research.

In his detailed and very informative article, Dr Bijan Kheirabadi discusses the research and development efforts to improve topical hemostatic agents that have been ongoing for the past 15 years or so. The need for a safe, effective, and easily used topical agent to control compressible hemorrhage has become an increasingly important goal for military medical researchers as the character of the battlefield has changed dramatically from that of years past. Planners have to anticipate longer evacuation times to surgical resources as current conflicts have become increasingly nonlinear, with dispersed locations of varying levels of medical and transport support. Statistically, the use of an effective hemostatic agent in

a dressing to quickly control hemorrhage in the prehospital phase of trauma treatment could be the most effective method to reduce morbidity in a significant percentage of casualties with compressible bleeding injuries. That fact, combined with the obvious utility of such agents in the hospital as well, focus the intense interest by researchers such as Dr Kheirabadi in developing the best product possible to meet our commitment to our nation's valiant Warriors.

COL John Kragh, Jr, and his coauthors address the most serious type of hemorrhage-related cause of death on the battlefield, the uncontrolled bleeding from a wound in the trunk area of the body, usually on the periphery of the body armor, for which tourniquet application is seemingly impossible. In 2009, the DoD Committee on Tactical Combat Casualty Care made truncal tourniquets a research priority. COL Kragh et al present a carefully developed, extensively researched discussion of the physiology of controlling truncal blood flow by compression, the anatomical considerations and challenges involved, the various attempts and ideas to address the problem throughout history, and some of the approaches under consideration in the current research. This article is an important look at perhaps the most important challenge facing those working to increase the survival of battlefield casualties during the prehospital phase of trauma care. Readers will have a thorough appreciation of the skills, expertise, and dedication of those addressing this complex and deadly, but unavoidable circumstance of combat.

Improvements in the Soldier's individual protective equipment used in current combat operations have resulted in a decrease in the number of lethal torso and head injuries, which means that surviving casualties present with various types of serious injuries in a larger proportion than previously experienced. That survivability, combined with the concussive effects of blast from the enemy's weapon of choice—the improvised explosive device—have resulted in a marked increase in diagnosed traumatic brain injury (TBI) among surviving combat casualties. As discussed in recent articles in the *AMEDD Journal*, TBI has become one of the signature injuries from the Iraq and Afghanistan combat theaters, and is the subject of extensive research and collaborative efforts to understand the physiology of this injury, and develop protocols to address it throughout the flow of casualty care. In their excellent, well-referenced article,

COL Leopoldo Cancio and MAJ(P) Kevin Chung present a detailed discussion of the research and clinical experiences shaping current thinking about how to best address TBI in the prehospital phase of trauma care. Their article focuses on stabilizing the casualty's respiration, ventilation, and blood pressure parameters within limits that have been indicated by studies as optimizing survivability and long-term recovery to normal brain functions. The information presented in this article is a compendium of the leading-edge of medical research in this increasingly important area, and should be of great interest to all medical professionals involved in any phase of combat trauma care.

The improved torso protection and the pervasive use of the IED have also resulted in an increase in the number of surviving casualties with severe burn injuries. The vast majority of those casualties are brought to the Burn Center at the Army Institute of Surgical Research (ISR), which has long been recognized as one of the world's premier burn care facilities. The Burn Center not only provides the best care possible to patients they receive, but it is also a major locus for research into all aspects of burn care, from point of injury to posttreatment rehabilitation. This is illustrated in the excellent article contributed by MAJ(P) Kevin Chung and his coauthors, which focuses on prehospital fluid resuscitation of the severely burned combat casualty. They investigated the actual fluid resuscitation practices of the prehospital providers caring for the burned wounded in comparison with the clinical standards recommended by the American Burn Association. Not surprisingly, they discovered that the complexity of fluid administration formulae and the close monitoring required was beyond the immediate capabilities of those charged with caring for multiple casualties in the stark surroundings of the battlefield. Indeed, their research found that prehospital responders in the United States were also not attempting to apply the detailed protocols to determine initial fluid rates. So the ISR developed and validated a greatly simplified methodology to calculate the initial fluid resuscitation rate which falls within the acceptable range. The patient's response then determines adjustments to that initial rate. The ISR had already (2005) developed and published burn resuscitation clinical practice guidelines for en route care, along with a flow sheet for standardized documentation of the care received by the patient throughout transport to the Burn Center. MAJ(P) Chung et al detail these efforts, as well as the development of a

computerized decision support system to further monitor and standardize resuscitation fluid rates. These and several other initiatives described in the article are indicative of the dedication, initiative, and enthusiasm for the mission that have been the hallmark of those professionals of the ISR who work tirelessly to save the lives of American Warfighters.

The capability to remotely monitor the physiologic status of Soldiers in the field has long been a staple of science fiction books and movies. However, the obvious value of such a concept has also been recognized by real-world military medical developers and researchers for many years. Dr Kathy Ryan and her team of coauthors provide a look at the current state of ongoing research and developmental work to produce a practical, reliable, and accurate system which, at the most basic level, will provide the combat medic a capability to remotely triage bleeding Soldiers. Combat medics routinely place themselves in vulnerable circumstances while finding, evaluating, and treating wounded Soldiers. Unfortunately, it is not uncommon for the medic to find the Soldier either not seriously injured, or too severely injured to be saved. Further, since the medics must make those judgments “on-site” requiring time and often risking their own lives, other seriously wounded Soldiers may wait, a potentially life-threatening situation. In their detailed, well-presented article, Dr Ryan et al examine the extreme complexities—physiological, technical, functional, and ergonomic—involved in designing the sensors, interfaces, and algorithms to present the information a medic needs to make the necessary critical judgments. The extent of the factors that researchers must consider is significant, but the analysis of specific data elements as to their respective contributions to presenting the overall physiological status is truly impressive. The effort described in this article is yet another example of the extraordinary level of expertise and capability that is found in the Army Medical Department.

As discussed from various perspectives in earlier articles, the scarcity of information about a casualty’s injuries, vital signs, and care received (including medications) is a continuing problem. In the absence of such information, each successive provider must take time to reevaluate the casualty as he or she moves through the various stages of the evacuation process, a delay which at any point in the process can be a very perilous circumstance for the wounded Warrior.

Further, that provider evaluation itself may be problematic, because in the dynamic environment of the combat theater, each caregiver’s level of experience and access to supporting medical information can vary considerably. As described by Dr Jose Salinas and his colleagues, mitigating these information shortcomings is the focus of ongoing research and development at the ISR, with the goal of providing prehospital medical caregivers with advanced computer-based monitoring and decision support systems (DSS) to minimize delays and sometimes dangerous variations in rendered care. Their ideal system would be one with multiple sensors on the patient feeding data into a DSS for analysis and presentation to the caregiver, who could query the system for previous care and medications rendered, access recommended procedures and knowledge-based information about the particular patient’s conditions and responses, and then monitor the patient’s condition in real time.

LTC(P) Robert Gerhardt provides an overview of the Army Institute of Surgical Research’s current efforts in research programs, development efforts, and collaborations aimed at improving casualty survival throughout the prehospital and transport phases of trauma care. Of course the ISR’s primary focus is the combat environment, but, as indicated by the close collaborations with other military services, civilian hospitals, trauma centers, and medical transport companies and agencies, the drive to optimize prehospital trauma care is a common goal for all practitioners of emergency medicine. Other articles in this issue have featured certain specific areas of work at the ISR, but LTC(P) Gerhardt’s article presents the scope of ongoing work across multiple areas, providing a perspective of the breadth and depth of the professional skills and capabilities which the dedicated people there bring to work every single day. It should also be obvious that the work at the ISR, although directed towards the survival of the Warrior on the battlefield, contributes greatly to the survival of trauma victims across the United States.

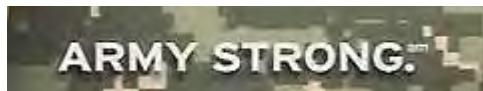
As MG Rubenstein mentioned in his opening remarks, the US Army combat medic is literally the point person in the sequence of trauma care that exists to stabilize a wounded Soldier until he or she reaches a surgical facility. This issue of the *AMEDD Journal* closes with 2 articles from LTC Robert Mabry and COL Robert De Lorenzo examining the training and certification requirements for those vitally important

individuals, and providing carefully-considered ideas and recommendations as to how to markedly improve their levels of skill and expertise. Of course the ultimate goal of any change is improved casualty survival rates in the prehospital phases of battlefield trauma care, a positive trend that is occurring, but can always be improved.

In their first article, LTC Mabry and COL De Lorenzo look at the historical evolution of the care of battlefield wounded, from literally none just a century or so ago, to the system of trained and skillful specialists with ambulances, helicopters, and specially configured medical transport airplanes that are part and parcel of modern battlefield trauma care. However, as good as it is, it can always be better, a proposition to which the authors are totally dedicated, with the ultimate goal of more lives saved. They call for renewed emphasis in the specific training and qualifications for those “out front” in the battlefield care path, not just the combat medics, but also the overseeing physician assistants and unit surgeons upon whom those medics rely for mentoring, instruction, and assistance. The authors point out that, in the past, military medicine was able to “grow our own” reservoir of experienced, skilled field practitioners, but certain factors currently limit that ability. They propose a number of structural changes and shifts in emphasis which would reinstate that depth of expertise, with only positive impacts on the numbers of surviving wounded who arrive at surgical facilities in combat theaters.

The advent of the helicopter as an evacuation vehicle for battlefield wounded is arguably one of the most significant developments in combat trauma care since 1797, when Dominique Jean Larrey established the world’s first formal ambulance corps for Napoleon’s armies. He recognized that time is life, a truism even more profound today as the capabilities of military medical practitioners have reached unimaginable levels, as long as the wounded reach them in time.

Indeed, as so often happens in history, the timing of the development of helicopter medical evacuation (MEDEVAC) was especially fortuitous in that it evolved in concert with momentous shifts in the nature of military operations. The Vietnam experience, followed by the collapse of the Iron Curtain, were strong indicators that future conflicts would probably not be fought over a “structured” battlefield, stretching back from the forward edge of the battle area through defined areas of support wherein vehicles could move via secured roads quickly and efficiently. Combat operations in Vietnam, Iraq, and Afghanistan have been, and are, dispersed, noncontiguous, and definitely nonlinear. Without the helicopter MEDEVAC, the prospects of our wounded Warriors reaching advanced medical facilities in time would be severely diminished. In their timely and important article, LTC Mabry and COL De Lorenzo argue that, as good as the military’s MEDEVAC capabilities are, they could and should be improved. They cite the areas where change would have the most significant positive results, and present proposals (and numbers) to enact those changes. They develop their recommendations based on the world’s most sophisticated, efficient, successful model of prehospital air transportation of trauma victims, the civilian system in the United States. As they point out, the irony of the situation is that the current US civilian emergency medical services system owes its existence to the success of the US military MEDEVAC operations in Vietnam. The excitement of early successes combined with enthusiastic state and federal support and resulted in rapid evolutions in sophistication, innovation, and capabilities, which have produced the superb system that benefits Americans in every state of our country. LTC Mabry and COL De Lorenzo present the case that the military’s MEDEVAC system should be closely and carefully reviewed with the goal of identifying and incorporating standards, protocols, and resources to optimize its lifesaving potential, and an already excellent system will only get better.



1831

COL Lorne H Blackbourne, MC, USA

INTRODUCTION

The year 1831 was very significant to the advancement of medical technology. It was the year of the first documented use of an intravenous fluid. It was administered to increase the intravascular volume to treat the signs and symptoms of hypovolemia.¹⁻⁴ In 1831, during the cholera epidemic in England, Drs Thomas Latta and Robert Lewins of London injected a saline solution guided by the pulse of hypovolemic cholera patients. Dr Lewins wrote in *The Lancet* about his experience with one patient:

The patient's pulse at the commencement was 180, very small and feeble. She was excessively restless, with a feeling of great weakness and tormenting thirst. Before 12 oz had been injected, the pulse began to improve; it became fuller and slower, and it continued to improve, until, after 58 oz had been injected, it was down to 110.³

Since this introduction of a saline-based intravenous fluid, how has the medical technology advanced that we are using prehospital on the battlefield prior to getting combat wounded to a surgical facility?

While the technology to locate, track, and destroy our enemies has taken huge strides since 1831, our prehospital technology to help save life and limb has not kept pace. Satellites, global positioning systems, unmanned aerial vehicles, and lasers are just a few of the new technologies placed on the modern battlefield; the modern combat medic is, on the other hand, using technology that has barely advanced since 1831. Highlighting the technologic advances in combat arms to the individual medic level, one only need look at the medic's semiautomatic sidearm, assault rifle (with electronic sights/laser), and night vision goggles, and then compare them to the flintlock rifle and flintlock pistol used in 1831. To illustrate the "technological divide," we must look at the medical technology available to combat medics today.

Guided by the tenets of Tactical Combat Casualty Care (TCCC), the training of medics today has greatly improved.⁵ The equipment manufactured for use by combat medics is lighter and is engineered with great advances. In contrast, when analyzed by comparing

anatomic injury diagnostic and treatment capabilities, the actual technology of the diagnostic and treatment options available on the battlefield does not reveal many great advances since 1831.

COMBAT INJURY DEMOGRAPHICS

Retrospective analysis indicates that the major causes of "potentially survivable" injuries resulting in death on the battlefield (killed in action) and after reaching a surgical facility (died of wounds) are truncal hemorrhage, "junctional" hemorrhage (axilla, groin, neck), extremity hemorrhage, airway, traumatic brain injury (TBI) and tension pneumothorax.^{6,7} Other areas of concern to combat medics include shock diagnosis, guidance of shock resuscitation, pain control, and remote triage.

COMBAT MEDIC TECHNOLOGY BY POTENTIALLY SURVIVABLE ANATOMIC INJURY

Truncal Penetrating "Noncompressible Hemorrhage" Injury

In combat, hemorrhage is the cause in 83% to 87% of all such potentially survivable deaths. Of these deaths, approximately 50% are due to noncompressible hemorrhage from penetrating truncal injury.^{6,7} The combat medic, when treating penetrating truncal (chest, abdomen, and/or pelvis) trauma on the battlefield, first diagnoses hemorrhagic shock by doing a manual check of the character of the patient's radial pulse and/or mental status (in the absence of TBI).⁵ Upon diagnosis of shock, the combat medic then administers an intravascular volume expander, either the starch based colloid Hextend (Hospira, Inc, Lake Forest, Illinois), Lactated Ringers (LR), or normal saline (NS) via an intravenous or intraosseous (IO) catheter. Since intravascular fluid administration is the only treatment option currently available to treat penetrating truncal trauma, and since there are no level I data that demonstrate improved efficacy of Hextend over LR or NS in the exsanguinating trauma patient in the prehospital setting, we cannot state that the technology to resuscitate/treat noncompressible truncal hemorrhage has advanced since 1831.⁴ Nor can we say that the technology available to the combat medic to diagnose hemorrhagic shock was not available in 1831. The addition of the IO infusion route is a clear

technologic advance in the patient without an antecubital vein for intravenous catheter insertion (rare) or, in certain tactical situations, due to white light restrictions.

Junctional Hemorrhage (Compressible, Nontourniquetable)

Current management of hemorrhage from areas that can be manually compressed but not amenable to tourniquet placement are described as compressible and nontourniquetable. These areas include the proximal femoral artery, distal iliac artery, axillary artery, and the carotid artery. Current management of these injuries includes manual compression with a hemostatic agent (currently Combat Gauze (Combat Medical Systems, Fayetteville, NC) is recommended by TCCC).^{8,9} Hemostatic agents represent a clear advance in technology over cloth bandage in 1831 as evidenced by animal data.

Extremity Exsanguination

During the “Victory of the Nile”* in 1798, a young French Midshipman recalled,

...the conflagration soon began to rage with dreadful fury... the French Commander-in-Chief, having lost both his legs, was seated with tourniquets on the stumps, in an armchair facing his enemy...¹⁰

And thus, our most important prehospital technology that has saved thousands of wounded Warriors in current overseas contingency operations is based on technology available over 200 years ago, an example of which is shown in the Figure.^{8,11,12}

Tension Pneumothorax

Tension pneumothorax is the cause of death in approximately 5% of combat wounded with potentially survivable injuries.⁷ On the battlefield today, a combat medic diagnoses a tension pneumothorax from observing the patient and, if feasible, by auscultation with a stethoscope. Dyspnea, distended Jugular veins, hypotension, and decreased unilateral breath sounds are the major findings for the diagnosis.

The stethoscope was invented in 1816 by René Laënnec in Paris, France.¹³ Since that time the stethoscope has improved but the basic technology has not. Physical exam and auscultation were available in 1831.

The treatment of a tension pneumothorax on the battlefield involves needle decompression by placing a

*In August 1798, the English fleet, under Rear Admiral Horatio Nelson, destroyed the French Mediterranean fleet anchored in Aboukir Bay at Alexandria, Egypt.

hollow needle through the second intercostal space in the midclavicular line.⁸

The first documentation of intravenous blood transfusion and intravenous pain medication administration is credited to Sir Christopher Wren in 1665 when he administered Opium via a sharpened quill to a dog.¹⁴ Since that time, multiple modifications have been made, including the invention of a hollow metal needle by Francis Rynd in 1844.¹⁵

The technology of observation, radial pulse determination, and auscultation to diagnose a tension pneumothorax were all available skills and technology available in 1831. And while the sterile decompression needles used today on the battlefield are an improvement over a sharpened hollow quill, the basic technology of decompressing a pleural cavity was available in 1831.

Hemothorax

Current guidelines for the management of hemothorax include diagnosis by physical exam and auscultation, and treatment with intravenous fluids and ventilator assistance with bag valve mask.⁵ The bag valve mask is clearly a technological advance, although there is no prospective data that demonstrates its use results in a mortality benefit in patients with a hemothorax.



Extremity tourniquet, circa 1760.

Open Pneumothorax (“Sucking” Chest Wound)

Current management guidelines for combat medics are to seal an open chest wound with an occlusive dressing and then observe for signs of a tension pneumothorax.⁸ Upon diagnosing a tension pneumothorax, the dressing is to be removed to allow for decompression. In 1823, Charles Macintosh applied for a patent for a waterproof cloth made with a rubber layer.¹⁶ And thus, a chest seal material technology was available before 1831.

PAIN CONTROL

Intravenous morphine is the most common analgesic administered on the battlefield.¹⁷ Narcotic analgesics based on opium were widely available before 1831.

REMOTE TRIAGE

...I flamed the bug and tossed a grenade and the hole closed up, then turned to see what had happened to Dutch. He was down but he didn't look hurt. A platoon Sergeant can monitor the physicals of every man in his platoon, sort out the dead from those who merely can't make it unassisted and must be picked up. But you can do the same thing manually from switches right on the belt of a man's suit. Dutch did not answer when I called him. His body temperature read ninety-nine degrees, his respiration, heartbeat, and brain waves read zero...

*Starship Troopers*¹⁸

The ability to know when soldiers are injured would help identify and locate wounded and maximize the time challenged opportunity to intervene. In 1831, as on the battlefields of 2010, the call of "MEDIC" is the most common way to remotely triage the wounded from those who are not.

PREHOSPITAL DOCUMENTATION

A review of the Joint Theater Trauma Registry reveals that less than 10% of entered patients had any prehospital

data, and that less than 1% had actionable information documented.⁸ Currently, prehospital documentation is obtained by manually completing a TCCC card. The technology to fill out a TCCC card is basically a pen and paper—both available in 1831.

MONITORS FOR THE DIAGNOSIS OF SHOCK

The medic on the battlefield uses physical examination to diagnose hemorrhagic shock and to guide resuscitation. Physical examination was available in 1831.

OVERVIEW OF OPPORTUNITIES FOR BATTLEFIELD CARE TECHNOLOGIC ADVANCES

It is certain that manufacturing, training, and some areas of battlefield care have advanced since 1831, but, as shown in the Table, the majority of anatomic injury diagnostic and therapeutic technologies have not.

OPPORTUNITIES FOR TECHNOLOGIC ADVANCES IN BATTLEFIELD PREHOSPITAL CARE

Penetrating Truncal Trauma

Intravenous fluids that allow for life-sustaining perfusion and oxygen delivery while ameliorating the acute coagulopathy of trauma could allow for extension of time until exsanguination and the severe effects of ischemia associated with the lethal triad and subsequent risk of death.^{4,19-21}

Comparison of available diagnostic and treatment technologies for the battlefield available in 1831 compared to 2010.

Diagnosis	Available Diagnostic Technology 1831	Available Diagnostic Technology 2010	Available Treatment Technology 1831	Available Treatment Technology 2010	Major Technologic Advance?
Penetrating truncal injury	Physical exam	Physical exam	Crystallloid	Crystallloid or colloid	NO
Intravenous access			Sharpened quill	Intraosseous catheter	YES
Extremity arterial hemorrhage	Physical exam	Physical exam	Tourniquet	Tourniquet	NO
Junctional compressible, nontourniquetable hemorrhage	Physical exam	Physical exam	Cloth packing	Combat Gauze	YES
Tension pneumothorax	Physical exam, auscultation	Physical exam, auscultation	Decompression with sharpened quill	Decompression with hollow needle	NO
Open chest wound	Physical exam	Physical exam	Waterproof cloth	Plastic sealant	NO
Hemothorax	Physical exam, auscultation	Physical exam, auscultation	Intravenous fluid	Intravenous fluid, bag valve mask ventilation	NO
Traumatic Brain injury	Physical exam	Physical exam	None	None	NO
Hypothermia prevention	Physical exam, thermometer	Physical exam, thermometer	Wool blanket	Active warming systems	YES
Prehospital documentation			Pen and paper	Pen and paper	NO
Pain control	Physical exam	Physical exam	Opium	Morphine	NO
Remote Triage			Voice	Voice	NO
Monitors for Shock and resuscitation	Physical exam	Physical exam			NO

Junctional (Compressible, Nontourniquetable) Hemorrhage

While current hemostatic agents represent a clear technological advance since 1831, the US military is only on the second generation of hemostatics. From a historical perspective, the future will most likely provide great improvement in these agents. A mechanical compression device for these junctional areas may also provide greater hemostatic capability in the near future.

Monitors for Diagnosing Hemorrhagic Shock

The medic on the battlefield uses physical examination, whereas the medic on an evacuation platform uses standard vital signs, both which, due to compensatory mechanisms, diagnose shock after significant blood loss (class III shock after loss of approximately one-third of total blood volume). With advances in resuscitation strategies, the ability to diagnose hemorrhagic shock before it is obvious and to guide that resuscitation over time will maximize the ability of combat medics to diagnose and treat combat wounded.

Remote Damage Control Resuscitation

As technologies for diagnosis and treatment for combat wounded become available, the remote presence of a physician, physician assistant, or any available professional with trauma expertise may offer an option for the medic. This capability option may offer the maximal application of the new technologies.

Tension Pneumothorax, Hemothorax, and Open Thoracic Wounds

The diagnosis of tension pneumothorax/hemothorax and laterality can be a major challenge to even the most seasoned traumatologist, especially in the face of concomitant blood loss. The diagnosis and treatment of tension pneumothorax on the battlefield today uses human skills and technology available in 1831. To improve the diagnostic accuracy and to monitor for recurrence, the advent of a pneumothorax/hemothorax detection system that is very small and of light weight would be a significant advance. Chest seals for open chest wounds with one-way valves would help decrease the chances of a recurrent pneumothorax and decrease the chances of having the medic decide whether or not to remove the dressing in the challenging patient with a sealed open chest wound. Safe methods for hemothorax/pneumothorax release with apposition of the visceral and

parietal pleura would seal off many sources of intrathoracic hemorrhage and air leak.

Battlefield Pain Control

Nonnarcotic pain control that allows for pain relief but that maintain the sensorium and judgment would turn the injured combatant on the battlefield from a liability to a potential force protection adjunct.

Hypothermia Prevention

Current hypothermia active warming blankets are clearly better than wool blankets.²² Future blankets will have improved ability to prevent heat loss and will progressively decrease in weight and volume.

Prehospital Documentation

Prehospital documentation of patient vital signs and therapeutic interventions with duration will maximize the admitting physician's ability to treat combat wounded. In civilian trauma, the documentation of accurate prehospital vital signs is associated with an improved outcome.²³ Recording prehospital vital sign trends is the first technologic goal.

For process improvement, a postevent, Web-based thorough reporting of all actions and life saving interventions used by the combat medic will provide the data needed to assist in training and overall assessment of prehospital medic performance. The 75th Ranger Regiment has such a Web-based program, the Prehospital Trauma Registry.

COMBAT REALITY OF TECHNOLOGIC ADVANCES

Our efforts to advance the technology available for combat medics must be made in concert with the end-user, the combat medic. "Buy-in" from medics is essential to the successful placement of all new devices and techniques. The size and volume of all advances must be within the capabilities of the medic and en route personnel to actually carry the equipment. Combat medics must be brought into the process of development of new battlefield technologies *for them* as early as possible.

CONCLUSION

The prehospital arena represents the geographic area with the greatest potential to improve care with advances in technology for wounded Warriors as they make the long journey from point of injury to rehabilitation in the continental United States.

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We Don't Know What We Don't Know: Prehospital Data in Combat Casualty Care

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*You can't improve what you can't measure,
and you can't measure without data.*

Caring for wounded warriors on the battlefield is an endeavor that resonates with every person who wears the military uniform of their country. The care provided by medical personnel in combat is often accomplished under the most difficult conditions imaginable and exemplifies the utmost in selflessness and courage. The challenges faced by medics, corpsmen, and pararescuemen in caring for their wounded teammates on the battlefield are legendary, and include an ongoing engagement with hostile forces, darkness, equipment limitations, and environmental extremes.¹

Process improvement in battlefield trauma care must focus on preventable causes of death. As with civilian trauma, death after injury occurs in a trimodal distribution with immediate, early, and late components. Immediate deaths are those who suffer overwhelming and catastrophic injury, particularly those in close proximity to explosive forces. Early mortality is characterized by mortality in minutes to hours and is largely the result of hemorrhage, anatomic and/or physiology respiratory compromise, or traumatic brain injury. The late spike in mortality is related to the sequelae of organ dysfunction. Many potentially lethal injuries, particularly those in the second phase, may be averted and late mortality mitigated by appropriate prehospital management of the injured patient.²⁻⁴ Within the context of military conflict, the overwhelming majority of battlefield casualty deaths occur before reaching a medical treatment facility, therefore, prehospital care is of paramount importance. Unfortunately, we have very sparse documentation of the actual care that occurs in the tactical setting. Of combat casualties, a recent analysis has extrapolated that 17% of battlefield fatalities could potentially survive under optimal circumstances.³ Of those potentially survivable

injuries, 79% of the mortality is secondary to hemorrhage, 12% to airway compromise, and 4% due to central nervous system injury.^{3,4} Mitigation strategies fielded to medics and corpsman are based upon the concepts of Tactical Combat Casualty Care (TCCC) and vary in some respects from those advocated by the civilian prehospital trauma life support. TCCC is focused on causes of preventable death on the battlefield and has a greater emphasis on tourniquets (combat application tourniquets), hemostatic dressings (Combat Gauze, Combat Medical Systems, Fayetteville, NC), needle decompression of tension pneumothoraces, and surgical airways. Although reports documenting the successes and failures of these and other TCCC interventions are available, the data are limited to small case series and individual reports.⁵⁻⁹

In contrast, tremendous advances in the management of the Wounded Warrior after he or she reaches a medical treatment facility have been driven by evidence. Derived from the necessity to improve the outcomes of Soldiers injured on the battlefield, US military forces developed and implemented the Joint Theater Trauma System and Joint Theater Trauma Registry (JTTR) using US civilian trauma system models. Using the civilian schema based upon the guidelines set forth by the American College of Surgeons,¹⁰ the trauma system implementation predicated the emplacement and evaluation of critical system component elements, including prehospital and acute care facilities, as well as infrastructure elements including trauma leadership, professional resources, performance improvement, research support, education, and advocacy.¹¹ The complexity of system care in the battlefield environment is compounded by the inherently discontinuous environment, and the necessity to maintain the continuum of patient care over several thousand miles involving 3 to 5 discrete levels of medical care. The constant in the under-

We Don't Know What We Don't Know: Prehospital Data in Combat Casualty Care

pinnings of success for the military trauma system has been evidence-based.

During the period between October 2001 and July 2010, 22,800 individual US military casualties were entered in the JTTR. Due to the inherent nature of active conflict, 87% of these casualties were classified as battle injury. The majority (66.4%) of battlefield casualties sustained a penetrating injury, 24.1% of all patients had an injury severity score of 16 or more, 21.8% had clinical evidence of shock with a base deficit of 5 or more, 24% of patients required blood, and 4.2% required massive transfusion (more than 10 units of red blood cells per 24 hours). Using these and similar data, tremendous advances have been made in the acute care management of the combat casualty, including advances in resuscitation of hemorrhage, burn resuscitation, and hypothermia prevention and management.¹¹⁻¹⁵

Collection of data regarding prehospital trauma care is inherently problematic. Even in the relatively mature civilian emergency medical service systems, there is a poor understanding of the effectiveness and utility of medical and procedural interventions in the prehospital management of trauma. Many therapies once dogmatically applied, such as military antishock trousers, large volume intravenous fluid resuscitation, and prehospital intubation of the traumatic brain injured patient, have fallen by the wayside after thorough investigation revealed that the practices were either not effective or deleterious to patient outcomes.¹⁶⁻¹⁸ These examples substantiate that most significant alterations in EMS management have come after thorough analysis of the data.

The tactical environment presents yet another tier of challenges in the evaluation of prehospital advances in treatment paradigms and technology with evidence.

Even the basic anatomic and physiologic metrics are uniquely difficult to obtain from the battlefield, due to the inherent dangers and complexities of the combat environment. To date, the limited, direct knowledge with respect to the outcomes from TCCC has only been obtained from the reports cited previously and other limited case series, as well as lessons learned vignettes by first responders describing their experiences with tactical trauma care.¹⁹ Though there is an evolving body of evidence that TCCC is responsible for saving lives on the battlefield, the vast

majority of the published peer review literature that support the efficacy of the concept of TCCC is rooted in the post hoc analysis of prehospital therapies identified at the level of a surgical treatment facility.²⁰

Tactical Combat Casualty Care is the latest evolution of the process of care within the hostile battlefield environment. The battlefield trauma care continuum is manifested by multiple coexistent levels of triage, treatment, and evacuation dissimilar to the civilian trauma setting. The current military combat casualty care paradigm consists of 5 discreet levels of injury care beginning at point of injury and finishing with casualty evacuation to the United States. The basic tenets of these tiered levels of battlefield injury care are aggressive stabilization, resuscitation, staged treatment, and evacuation of the wounded to progressively higher levels of care to improve injury outcomes while being sensitive to the realities of the resource-constrained environment of operations. Prehospital casualty care is initially manifest with self aid and may progress through a sequence of buddy aid to combat life saver (nonmedical). The first medically trained support within the chain for the injured combatant is the combat medic, corpsman, or more highly trained special operations medic. The goal of medical management at this echelon is to expeditiously stabilize the casualty for evacuation to the next appropriate level of care. Some of the unique facets of care in the combat environment include care under hostile fire, austere environments, potential for prolonged time period between injury time and evacuation time, limited senior medical guidance, and limited resources.

However, the prehospital period is the critical missing link in the care of the US military combat casualty. A recent analysis of 3 years of trauma data from the JTTR, shown in the Figure, was significant in that the vast majority of battlefield casualties (87%) had no documentation at all of prehospital wounding mechanism, injury location, vital signs, or interventions. Of a sample of 4,382 casualties in the registry from August 2007 through March 2010, only 8% had complete vital signs, and only 6% had any documentation of therapeutic intervention or attempt from point of injury. The net effect is that the medical and research and development communities will continue to develop new technologies to support the combat casualty care needs of the Warfighter based upon suboptimal evidence.

The acquisition of prehospital data is paramount to the lifesaving ability of the frontline medic, and ultimately to the survival of the combat casualty. The lack of documentation of rudimentary physiologic measures (ie, heart rate, systolic blood pressure, respiratory rate) in the field is associated with a more than 2-fold increased risk of mortality which was sustained even after adjustment for severity of injury.²¹ Some of this increased mortality risk probably results from the inability to study such data and implement performance improvement measures. Emphasis placed upon enhancing the quality and quantity of prehospital documentation within the civilian EMS community has proven to be efficacious and sustainable.²²

There have not been, nor will there be, prospective randomized trials conducted in the battlefield environment, and yet there must be some basis for process improvement in prehospital combat casualty care. The Department of Defense Committee on Tactical Combat Casualty Care makes recommended changes to the TCCC Guidelines based on:

- an ongoing review of the published civilian and military prehospital trauma literature,
- ongoing interaction with military combat casualty care research laboratories,
- direct input from experienced combat corpsmen, medics, and pararescuemen,
- case reports discussed on the weekly Joint Theater Trauma System performance improvement trauma teleconferences,
- regular interaction with the service military medical lessons learned centers, and
- expert opinion from both military and civilian trauma leaders.¹

Improved documentation of combat injuries sustained, treatments rendered on the battlefield and during evacuation, and results of interventions performed would be an invaluable addition to this process.

There are effective systems available at present to markedly improve our ability to document the prehospital care provided to our Wounded Warriors. The TCCC Casualty Card and the Prehospital Trauma Registry, both pioneered by the 75th Ranger Regiment, offer the immediate availability of a systems improvement in this area. These options have been recently endorsed to the services by the Defense

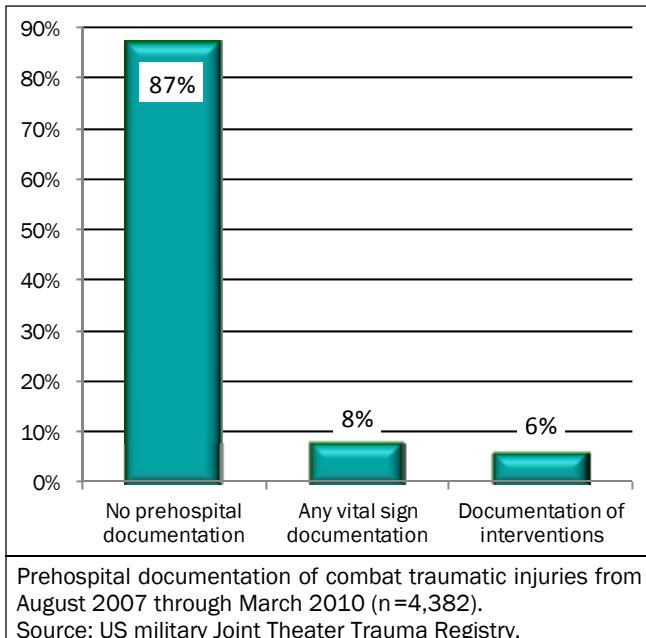
Health Board in their memorandum of August 6, 2009.²³ The TCCC Casualty Card has been recently designated as a standard Army form (DA7656).

Most preventable deaths occur in the prehospital phase. This interval is where the next great leap forward in combat casualty care could be. Recommendations for the immediate way ahead:

- Line commanders take ownership of ensuring that their troops complete the TCCC Casualty Cards.
- Deployed medical commanders ensure that the data is transcribed from the cards and the registries into the electronic medical records and the JTTR.
- Medical research leaders provide resources for the data to be rapidly collated and systematically analyzed, and make recommendations for process improvement.
- Both military medical leaders and line commanders respond in a timely manner to implement improvements suggested by this newly available data.

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A Prehospital Trauma Registry for Tactical Combat Casualty Care

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ABSTRACT

Many combat-related deaths occur in the prehospital environment before the casualty reaches a medical treatment facility. The tenets of Tactical Combat Casualty Care (TCCC) were published in 1996 and integrated throughout the 75th Ranger Regiment in 1999. In order to validate and refine TCCC protocols and procedures, a prehospital trauma registry was developed and maintained. The application of TCCC, in conjunction with validation and refinement of TCCC through feedback from a prehospital trauma registry, has translated to an increase in survivability on the battlefield.

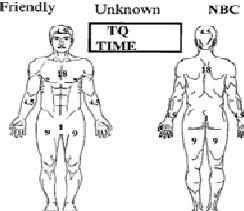
Historically, many combat-related deaths occur in the prehospital environment before the casualty reaches a medical treatment facility.¹ In 1996, Butler and colleagues outlined a novel approach to prehospital trauma management that would optimize casualty care in unique environments and circumstances encountered during combat operations.²

The 75th Ranger Regiment adopted and integrated the principles of Tactical Combat Casualty Care (TCCC) in 1999. Because all personnel on the battlefield have the potential to provide casualty care as first responders, and also have the potential to be a casualty, the 75th Ranger Regiment provided TCCC training to all personnel assigned to the unit. The Ranger First Responder Course and the Casualty Response Training for Ranger Leaders Course were 2 TCCC-based programs of instruction developed and implemented at that time to ensure a mastery of the basics of TCCC by all Rangers.³ Additionally, the Regiment integrated the principles of TCCC in the same manner as a battle drill during the conduct of training exercises and rehearsals for combat raids and airfield seizures.

Documentation of prehospital care provides a historical record of the event on behalf of the patient and communicates patient status, injuries, and treatments as patients flow from provider to provider on the battlefield. Documentation of injuries and prehospital treatment is also required to validate and refine TCCC protocols and procedures. Although the DD Form 1380 (Field Medical Card) was the standard

for military prehospital care documentation at that time, it did not adequately capture the necessary data fields imposed by TCCC. Thus, also in 1999, the 75th Ranger Regiment developed a casualty card to capture and document TCCC in the prehospital environment. This card quickly propagated throughout the US Special Operations Command and was used by multiple units in both Afghanistan and Iraq. Most recently (2009), this card, shown in the Figure, was adopted by the US Army as DA Form 7656, Tactical Combat Casualty Care Card.

Once again, as all personnel on the battlefield have the potential to be first responders, TCCC equipment and supplies must be considered to be “Soldier-centric” and should be commensurate with ability, skills, and training. Thus, in 2000, basic TCCC bleeder control kits were provided to all Rangers and were carried in a

A: Intact Adjunct Cric Infubated	Name/Unit _____
B: Chest Seal NeedleD ChestTube	DTG: _____ ALLERGIES: _____
C: TQ Hemostatic Packed PressureDrg	Friendly Unknown NBC
FLUIDS: IV TO NS / LR 500 1000 1500 Hextend 500 1000	TQ TIME
Other: DRUGS (Type / Dose / Route): PAIN ABX OTHER	
	GSW BLAST MVA Other
	TIME _____
	AVPU _____
	PULSE _____
	RESP _____
	BP _____
First Responder's Name _____	
DA FORM 7656	

The Tactical Combat Casualty Care Card, DA Form 7656.

A Prehospital Trauma Registry for Tactical Combat Casualty Care

standardized fashion and location to facilitate rapid self or buddy care, while medics carried additional medical equipment and supplies for more advanced care. It should be noted that the Ranger bleeder control kit subsequently became a model for the Army's current individual first aid kit.

As first responders were ultimately providing casualty care, and at times found themselves in combat formations that did not include a medic, responsibility for documentation of this care was shifted away from the medic only to all Soldiers, in contrast to the Field Medical Card traditionally carried solely by the medic. Thus, Ranger casualty cards became ubiquitous and were included in all bleeder control kits. As such, they were collocated with all potential first responders as well as all potential casualties.

Prompted by the events of September 11, 2001, components of the 75th Ranger Regiment deployed to combat in Afghanistan the following month. Concurrently, the 75th Ranger Regiment initiated a casualty card collection program in order to capture and evaluate data on combat casualties and casualty treatments. The casualty card collection program expanded to Iraq in March 2003 as components of the 75th Ranger Regiment also deployed in support of combat operations in that theater.

Although initially a rudimentary database in its nature, the casualty card collection program evolved into a prehospital trauma registry (PHTR) in 2005 using the Ranger casualty card as the template for the registry. Post hoc PHTR casualty card entry removed battlefield chaos and ensured increased capture and granularity of injuries incurred and treatments provided. Command emphasis and support of the PHTR was instrumental to its success. Leaders viewed the casualty card collection program and PHTR as a means to answer questions in reference to personal protective equipment as well as tactics, techniques, and procedures. Lessons learned were rapidly dispersed internally throughout the organization and externally to other units. Integral to gaining and maintaining command support for the PHTR were the integration and front loading of instant data graphing products, command reports, and ad hoc query capabilities into the PHTR. Notable is that the PHTR significantly increased the success of the casualty card collection program. Also of note, utilizing the casualty card in isolation would not have

adequately provided the purpose, justification, and feedback required to maintain strong command support for the program.

The purpose of the PHTR was to collect combat point-of-injury data at near-real time and provide timely command-level data, statistics, trends, and analysis. Thus from 2008 to 2010, in consultation with the US Army Institute of Surgical Research and in collaboration with the Texas A&M Health Science Center Rural and Community Health Institute, the framework and power of the PHTR was further refined as medics and computer programmers worked side by side to develop a product that would benefit the command. The resulting PHTR is a web-based solution specifically developed in order to validate TCCC training and treatment protocols through an internal assessment and analysis of casualty wounding patterns and treatments rendered. This analysis would determine if appropriate interventions were conducted on casualties who needed them, if there was a lack of appropriate interventions on casualties who needed them, and if inappropriate interventions were conducted on casualties who did not need them. Ultimately, the analysis would also help to facilitate 5 major goals:

1. Augment the commander's decision-making process.
2. Reduce morbidity and mortality through force protection modifications and directed procurement.
3. Validate and refine the commander's casualty response system.
4. Evaluate current Tactical Combat Casualty Care treatment strategies.
5. Guide needed modifications to unit medical and nonmedical personnel, training, and equipment requirements.

Requirements for point-of-injury, tactical, and level 1 care and documentation must reflect the fact that the current flow of casualty care is no longer based on strict adherence to historical echelons of care. Proposed technological solutions cannot detract from the combat mission, hinder combat casualty care, or put a task force at risk. Material solutions must remain simple, durable, redundant, and ubiquitous. Solutions must also be Soldier-centric and not medic-centric, as all Soldiers have the potential to be first responders.

As TCCC implementation is the responsibility of tactical leaders, it is a “casualty response system” and not a “medical system.” Providing timely feedback to tactical leaders is a must in order to affect needed changes in tactical force protection and procurement requirements, TCCC treatment strategies, and resourcing of personnel-training equipment.

The 75th Ranger Regiment has been continuously engaged in combat operations throughout the past 9 years. As such, the Regiment has maintained a constant presence in Afghanistan since 2001 and Iraq since 2003. The Ranger casualty card and PHTTR have been successfully used in both theaters throughout this time. As of April 1, 2010, the Regiment had sustained a total of 419 battle injuries, including 28 who were killed in action and 4 who died of wounds. None of these fallen Rangers passed away as a result of prehospital medically preventable causes.

Tactical Combat Casualty Care must be measured, validated, and refined through a functional PHTTR that provides evidence-based support for casualty care protocols, procedures, and training. Documentation of injuries and treatments in the prehospital environment has proven instrumental in the continuous refinement and improvement of TCCC treatment strategies at the unit level. Point-of-injury and prehospital wounding and treatment data captured by the PHTTR can also be linked to patient outcomes maintained at the Joint Theater Trauma Registry for optimal analysis of the entire provided continuum of care. Innovation and advancement of casualty care on the battlefield is facilitated by a care delivery system with a data repository which is available for data mining by investigators and researchers.

Ultimately, TCCC is not just a medical program; it is the framework of a casualty response system that relies

on a mastery and immediate application of basic and vital lifesaving skills by all Soldiers. This is validated by a PHTTR. The success of TCCC is directly related to command ownership of the program. The tactical commander owns and is responsible for the prehospital casualty response system, and all personnel in the command serve as the foundation for prehospital care on the battlefield. TCCC provides the critical protocols and procedures necessary for Soldiers to treat a casualty. Leaders ensure this training is conducted to standards and is rehearsed and integrated into training events throughout the training cycle. The PHTTR continuously validates and refines TCCC. The end result is an increase in survivability on the battlefield and a successful completion of the mission.

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Current Concepts in Fluid Resuscitation for Prehospital Care of Combat Casualties

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ABSTRACT

Historically, hemorrhage accounts for the primary cause of death on the battlefield in conventional warfare. In addition, hemorrhage was associated with 85% of potentially survivable deaths in the current conflicts, approximately two-thirds of which were from noncompressible injuries. Future combat casualty care strategies suggest the likelihood of long transport times or significant time delays in evacuation of casualties. In addition, there are logistical limitations to providing large volumes of resuscitation fluid far-forward, and current guidelines do not recommend infusing large volumes of fluid until bleeding is controlled. Since the medic has few options for treating noncompressible injuries short of infusing fluid to maintain a blood pressure, the concept of damage control resuscitation was developed to promote hemostatic resuscitation. Damage control resuscitation recommends limiting the amount of crystalloids or colloids infused and using plasma and other blood products in more optimal ratios for the treatment of severe hemorrhage to improve battlefield survival and to reduce or prevent early and late deleterious sequelae. Taken together, these efforts have important implications towards the development of optimal fluid resuscitation strategies for stabilization of the combat casualty.

INTRODUCTION

It is reported that acute hemorrhage consistently accounts for about 50% of battlefield deaths in conventional warfare, and for 30% of casualties who die from wounds.¹ In addition, lessons learned by the British, the Israelis and the Indians in their various conflicts and skirmishes confirmed that prompt resuscitation improves survival.^{2,3} Also, results of a consensus conference and studies of pulse status concluded that fluid resuscitation was necessary for any casualty with a change in mental status or who was unconscious, suggesting a systolic blood pressure less than 50 mm Hg.^{4,5}

It is well recognized that limitations exist in providing sufficient fluid for resuscitation in far-forward combat environments. Weight and cube limitations restrict the availability of large volumes of crystalloid resuscitation fluids for far-forward use. In addition, the combat medic has limited training, and long evacuation times or delayed transport to forward surgical facilities can be expected. Future combat scenarios imply that delays of 24 hours before evacuation of casualties could be more common, particularly if evacuation is from urban environments, as was experienced in Somalia.⁶ The implication is that several hours may pass before any surgical intervention is possible to treat the injured Soldier. As indicated by Bellamy,¹ mortality increased from 20% to 32% when evacuation

of casualties was delayed from immediately to 24 hours. Yet, evidence from experimental animals suggests that interventions to reestablish homeostasis may need to be initiated within 30 minutes after injury to assure survival,⁷ offering additional challenges to attempts to improve resuscitation on the battlefield and at higher echelons of care.

Addressing the need for improved prehospital fluid resuscitation for treating traumatic hemorrhage was the topic of an ISR-sponsored symposium held in January 2010. The current tactical combat casualty care guidelines were evaluated along with the goals that an ideal resuscitation fluid should expand and maintain circulating blood volume, and thus vital organ perfusion, while having a positive effect on hemostasis. The current state-of-the-art use of crystalloids, colloids, and oxygen carriers were discussed. The discussion led to the conclusion that current fluid resuscitation guidelines are not optimal and further research was needed for prehospital resuscitation.

DAMAGE CONTROL RESUSCITATION

Autopsy data from about 1000 casualties in Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) have identified hemorrhage as a cause of death in 85% of potentially survivable casualties, and bleeding could only have been controlled in 32% of these casualties by means presently available to the

field medic, such as tourniquets and hemostatic dressings.⁸ For the remaining 68% with noncompressible hemorrhage, the medic has few options at present, other than fluid to maintain blood pressure until the casualty can get to a surgeon. In addition, it is well recognized that trauma patients can develop coagulopathy. For years it has been reported that trauma patients can become hypothermic and acidotic which, along with the development of a coagulopathy, forms a triad known as the “bloody vicious cycle” with a high mortality rate.⁹ Routine care has been to warm these patients and reverse their acidosis, which has been successful.^{10,11} However, little has been done to address their bleeding abnormalities until the patient went to the operating room. In addition, it has recently been recognized that traumatic injury can early induce a bleeding disorder that is independent of the development of hypothermia or a result of hemodilution, and is commonly seen in the most severely injured patients who require a massive transfusion.¹²⁻¹⁴ This observation initially seen in the civilian community was also recognized in a military population,¹⁵ representing about 38% of casualties requiring a transfusion. Data show that coagulopathy is related to severity of injury and markedly increases mortality rates at similar levels of injury severity. Improving survival at all echelons of care in these patients requires hemorrhage control and resuscitation to restore normal blood clotting capabilities and metabolic processes, while providing volume. Current guidelines provided by the Committee on Tactical Combat Casualty Care advocate the control of bleeding and limited fluid resuscitation with Hextend (Hospira, Inc, Lake Forest, IL), allowing the systolic blood pressure to rise to around 80 mm HG. Over the past 40 to 50 years, the treatments commonly used for resuscitation of hemorrhagic shock in both the civilian and military sector, including crystalloid solutions and packed red blood cells, actually dilute the remaining coagulation factors and platelets further which may increase the tendency for more bleeding.

An evaluation of patients at Combat Support Hospitals from January 2004 to December 2006 revealed that 90% suffered from penetrating trauma, with hemorrhage being the number one problem.^{15,16} Of these patients, 22% required a transfusion and over 8% required a massive transfusion, defined as 10 or more units of packed red blood cells (RBCs) in a 24-hour period. In comparison, at a major trauma center in the

United States, 11% required a transfusion and only 2.7% of those required a massive transfusion. Considering the much greater magnitude of injuries and the over 3 times higher need for massive transfusion encountered in OIF and OEF compared to civilian trauma,¹⁷ the requirement for more effective treatment is more of an urgent problem for the military. Since patients who require massive transfusion generally comprise the majority of in-hospital trauma deaths, there was a need for a revolutionary strategy to treat such severe injuries.

To address the above problems, the concept of damage control resuscitation (DCR) was introduced as a resuscitation strategy primarily for the most seriously injured patient. It is a structured intervention that consists of 2 goals and was endorsed Army-wide in January 2007 for optimal resuscitation of severely injured Soldiers. The first goal is to limit fluid resuscitation to keep the patient’s systolic blood pressure at about 80 mm HG to minimize renewed bleeding from recently formed blood clots.¹⁸ The second goal is to restore the blood volume using plasma as the primary resuscitation fluid in a ratio close to 1:1 with RBCs to provide hemostatic resuscitation. Other blood products reserved for massive transfusion protocols, such as platelets, cryoprecipitate, and, possibly, recombinant activated Factor VII and fibrinogen which are available and could be used as needed.

PERMISSIVE HYPOTENSION

Permissive hypotension, or fluid resuscitation to a blood pressure lower than normal, was recognized as a reasonable approach in the care of combat casualties in both World Wars I and II.^{19,20} Adaptation of permissive hypotension as a far-forward treatment strategy was renewed by US Special Operations Forces after a 1998 conference.⁵

Today, fluid resuscitation practices to normalize the blood pressure rapidly after traumatic hemorrhage are no longer recommended, especially in patients with penetrating injuries.^{21,22} Rapid volume infusion even for blunt trauma patients is also being questioned.²³ It has been argued that resuscitation to baseline or normal blood pressure can increase bleeding and worsen outcome because of severe hemodilution of remaining coagulation factors and hemoglobin, as well as disruption of newly forming blood clots. Thus, it is suggested that permissive hypotensive resuscitation

can improve outcome, yet avoid these adverse hemostatic and metabolic effects.^{21,22,24,25} As an example, studies in both rodents and swine have shown that in the treatment of uncontrolled hemorrhage from a vascular injury, restoring mean arterial pressure to 40 mm HG or 60 mm HG, resulted in longer survival compared to animals resuscitated to the baseline mean arterial pressure of 80 mm HG, as well as animals that received no fluid.^{26,27} In addition, the provision of some fluid even before surgical repair of the injury is performed also appeared to be better than delaying all fluid until after surgery.²⁶ Also, our own work observed that lactated Ringer's (LR) infusion to a mean arterial pressure (MAP) of 70 mm HG improved hemorrhage-induced vascular hyporeactivity to norepinephrine better than LR resuscitation to baseline MAP during the 4-hour study period.²⁸ Resuscitation to baseline MAP with LR resulted in severe hemodilution and deterioration of vascular responsiveness to norepinephrine. The medical literature contains several studies reporting on adverse immunologic effects of LR or normal saline,^{29,30} so efforts to reduce the volumes used seem prudent. However, the adequacy of hypotensive fluid resuscitation is not well delineated as some studies have suggested that hypotensive crystalloid resuscitation to a MAP of 60 mm HG to 70 mm HG may be inadequate to prevent metabolic derangements associated with hemorrhagic shock.^{31,32} It should be noted that over the last decade of research into hypotensive resuscitation, the majority of studies have only monitored animals for a few hours, and LR or normal saline has been the primary fluid examined.^{33,34} Since not all animals in the hypotensive resuscitation groups survived in some of the studies, research into better resuscitation strategies and improved fluids seems warranted.

BLOOD AND BLOOD COMPONENTS

As mentioned, the second major aspect of damage control resuscitation recommends a judicious use of blood products in more favorable ratios to improve outcome in the severely injured, particularly in patients requiring a massive transfusion. This aspect of DCR is focused on addressing the coagulopathy associated with traumatic injury through hemostatic resuscitation. Adverse effects of RBC transfusion are well described,³⁵⁻³⁹ so determining which patients need blood is another area of research at the US Army Institute of Surgical Research (USAISR).

Damage control resuscitation practices in theater were implemented through a Joint Theater Trauma System Clinical Practice Guideline* (last updated February 2009) for the use of blood products at level IIb/III. Of course, the use of blood by the US military is not a new idea and transfusion practices date back to World War I. Blood use in World War II,⁴⁰ the Korean conflict,⁴¹ and in Vietnam⁴² have been described. This history has also been extensively reviewed by Hess and Thomas.⁴³

Several retrospective reviews have analyzed military casualty data from combat support hospitals and have concluded that use of plasma, including plasma to RBC ratios that approached 1:1, improved the coagulopathy and reduced 30-day mortality compared to the use of more RBCs or ratios of plasma to RBCs greater than 1:4.⁴⁴⁻⁴⁶ Prospective studies in swine polytrauma models have also shown that plasma alone could improve coagulopathy.⁴⁷ Other studies observed improved survival with greater use of platelets and the benefits of higher fibrinogen to RBC ratios.^{48,49} Also of interest is the successful use of warm, fresh, whole blood in theater where over 6000 units have been transferred over a 4 to 5 year period.¹⁶ Retrospective studies have seen improved 30-day survival with warm, fresh, whole blood compared to casualties who received component therapy, as well as acceptable benefit-to-risk ratios under situations where blood components are unavailable or not available in sufficient amounts for transfusion requirements.^{16,50,51}

Retrospective reviews of greater use of plasma and higher plasma to RBC ratios have also been assessed in civilian trauma patients. More aggressive use of plasma seems to be beneficial in improving coagulopathy.^{11,52} Further evaluation suggested that achieving near a 1:1:1 ratio of plasma, RBC, and platelets improved the coagulopathy and had a positive impact on survival.⁵³⁻⁵⁷ However, the optimal ratios remain controversial.^{58,59} Taken together, the data suggest that DCR practices improve outcomes in coagulopathic trauma patients by using more plasma and other blood components in ratios closer to whole blood, and by reducing the use of large volumes of crystalloids in the resuscitation.

As the current use of blood products for treating severely injured trauma patients has occurred in

*Internal military document not normally accessible by the general public.

medical treatment facilities, interest has been generated regarding having plasma available in the prehospital or far-forward setting. It is well known that freeze-dried plasma was extensively used for resuscitation in forward areas during World War II, but was withdrawn due to high transmission rates of hepatitis.⁴⁰ Efforts are currently underway to redevelop a freeze-dried plasma product for use in the United States. Recent studies in a swine polytrauma model showed that freeze-dried plasma was similar to fresh-frozen plasma in its coagulation factor levels and could improve the coagulopathy in this model.^{60,61} Currently, freeze-dried plasma is available through the German Red Cross and the French Military, and both products are available for use by coalition medical personnel in Operation Enduring Freedom (Afghanistan).

CONCLUDING REMARKS

Prehospital resuscitation practices and the use of crystalloids for fluid resuscitation have not changed significantly in the past 40 to 50 years in either the military or civilian sector. Through research funded primarily by the US Army Combat Casualty Care

Research Program, efforts in the past 20 years have been directed on improving far-forward resuscitation. Current investigations on fluid resuscitation strategies at USAISR are now focused under the concept of damage control resuscitation. Despite efforts to provide small volume resuscitation through development of hypertonic fluids such as hypertonic 7.5% saline without or with Dextran-70 (hypertonic saline/dextran) over the past 20 years, these products have yet to achieve FDA approval, although a 5% saline solution is FDA approved for hyponatremia. Consequently, for the past decade the Tactical Combat Casualty Care committee recommended Hextend, a hetastarch based product in a balanced salt solution, as the fluid of choice for small volume resuscitation, with guidance to limit the total infusion to one liter based on the casualty's mental status or pulse character.⁴ No fluid is recommended if the casualty is not in shock.

As noted, to date most fluid resuscitation studies evaluating this permissive hypotension have generally used crystalloids such as LR or normal (physiologic) saline. Our own studies in a swine hemorrhage model have indicated that similar hemodynamic and meta-

Damage control resuscitation research areas at the US Army Institute of Surgical Research	
General Resuscitation	Hemostatic Agents
Adequate Volume	Dressing for external wounds
Hypotensive resuscitation	Tourniquets and junctional devices
Temperature of fluid	Intracavitory bleeding
Choice of fluid	
Metabolic derangements	
Adjuncts (metabolic substrates, antioxidants, sex hormones, etc)	
Immune Modulation	
As related to standard therapy in patients	
Interactions with coagulation system (animals/trauma patients)	
Complement components	
	Biomarker of Resuscitation
	Hypoxia signals and cellular susceptibility
	Improvement by resuscitation?
	Newer Blood Products (in collaboration with Blood Research Program)
	Freeze dried plasma
	Refrigerated/frozen/freeze-dried/spray-dried platelets
	Dried/freeze-dried red blood cells
	Freeze-dried/recombinant fibrinogen
	Hemoglobin-based oxygen carriers
	JTTR retrospective review (outcome data)
	Use of blood products
	Coagulopathy
	Clinical Studies
	Assessment of blood product use in trauma patients
	Resuscitation Outcomes Consortium (Joint effort of Department of Defense and National Institutes of Health)
Endothelial cell function, interactions, effect of laminar flow	

bolic responses can be achieved with about a third of the volume using colloids compared to crystalloids in swine resuscitated to 80 mm HG systolic pressure.⁶² However, the limits of this hypotensive resuscitation strategy, such as whether permissive hypotension would worsen the incidence of late complications that could arise from incomplete resuscitation, are unknown. Also, evidence does suggest that resuscitation to a systolic blood pressure of 80 mm HG would be inadequate to improve cerebral perfusion after head injury. Thus, a component of DCR research at USAISR investigates adjuncts that can be used in small volume resuscitation (<2 ml/kg). This work is in conjunction with the Defense Advanced Research Projects Agency Surviving Blood Loss Program. Preliminary studies in a swine severe hemorrhage model have shown some benefit associated with small volume estrogen infusion.⁶³ An overview of research projects at the USAISR under the damage control resuscitation program is presented in the Table.

At present, the clinical practice guidelines for use of warm, fresh, whole blood or plasma and other blood components as part of a damage control resuscitation regimen are designed for level IIb/III echelons of care. As mentioned, the approach is to treat the most severely injured who present with a coagulopathy and

have the greatest chance of dying. Typically, these are the patients who require a massive transfusion. However, efforts are underway to move this DCR strategy to more forward echelons of care, and current research efforts focus on the development of freeze-dried plasma and platelet-like substances, as well as other components derived from plasma such as fibrinogen concentrates and recombinant activated factor VII. The consensus of discussants at the USAISR-sponsored symposium on prehospital fluid resuscitation overwhelmingly favored the development of a dried plasma product that could expand and maintain blood volume while providing lost coagulation factors resulting from the traumatic injury. Thus, this further supports expanding DCR capabilities to the prehospital arena. Damage control resuscitation guidelines emerged from a recognized medical problem and are being addressed by preclinical and clinical studies to develop an evidence-based best practice for treating these severely injured Soldiers. It is hoped that early implementation of far-forward damage control resuscitation will result in fewer early deaths from hemorrhage and fewer medical complications, such as development of multiorgan failure and related sequelae, as well as overall reduction in blood product use.

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Evaluation of Topical Hemostatic Agents for Combat Wound Treatment

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ABSTRACT

Uncontrolled hemorrhage remains the leading cause of potentially preventable death in combat casualties. In the current conflict, nearly two-thirds of these deaths occurred as a result of torso injuries with noncompressible hemorrhage and one-third from extremity injuries with compressible bleeding. The natural ability of blood to clot rapidly and stop bleeding from large vessels is far less than needed in the face of severe injuries and may even be diminished as a result of a massive tissue trauma (acute coagulopathy). Therefore, the use of a pressure device (ie, tourniquet) or topical hemostatic dressing is essential to stop compressible hemorrhage and prevent possible shock or death of casualties at the point of injury. To provide combat medics with the best means of treating hemorrhages, it is essential to understand the mechanism of action, efficacy strength, and possible adverse effects of each available hemostatic agent. In this article, we review the risks and benefits of the agents/dressings that have been used on the battlefield, the process that led to the selection of the new agents, and the present deficiencies that must be addressed in the development of new products.

INTRODUCTION

In current military operations, as in the past, severe bleeding wounds that cannot be treated with standard hemostatic methods remain the number one cause of potentially preventable death among combat casualties.¹⁻³ An early and effective method of controlling hemorrhage at the point of injury or after the casualty reaches the surgical facility can potentially save more lives than any other measure.^{4,5} Tissue trauma and hypovolemic shock caused by significant blood loss are additional risk factors that can lead to acute coagulopathy, making hemorrhage control and resuscitation therapy more difficult even after patients arrive at the hospitals.^{6,7} In addition to the need for immediate surgical intervention to control hemorrhage, more blood and blood products transfusion are required to reverse shock and restore normal coagulation in these patients. When the bleeding is eventually stopped after significant blood loss and resuscitation therapy, the patients are left more vulnerable to hypothermia, acidosis, and persistent coagulopathy, and are at higher risk of morbidity and late mortality due to sepsis and multiple organ failure that may occur afterwards.^{8,9}

Battlefield mortality (killed in action) resulting from traumatic wounds has significantly diminished in the ongoing military operations as compared to previous conflicts.^{10,11} This decrease is likely due to several

factors, including routine wear of body armor, prompt and efficient use of tourniquets to stop extremity bleeding, rapid casualty evacuation, and aggressive use of plasma along with red cells for fluid resuscitation.¹¹ A recent epidemiological study of combat wounds received in Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) showed that extremities were the most common sites of injury among the casualties, of which the majority were not lethal and amendable by tourniquet application.¹² A review of lethal wounds in autopsy reports of 982 combat deaths in Iraq and Afghanistan revealed that nearly 24% could have been potentially prevented if early and effective treatments had been provided. Of those potentially preventable deaths, 85% were caused by uncontrolled hemorrhage, of which two-thirds were noncompressible and one-third compressible bleeding.¹³ These findings once again emphasize the need for prompt and more effective hemorrhage control treatment in the field and in the combat support hospitals. Because of the possibility of prolonged evacuation times during combat operations and limited options before the arrival of casualties at the combat support hospitals, the prehospital phase offers the best opportunity to control hemorrhage at its early onset, and prevent morbidity and mortality consequences.^{14,15}

It is clear that the natural ability of blood to clot rapidly and seal bleeding vessels is inadequate to stop a more severe hemorrhage, and that this mechanism

may even be weakened after massive tissue injuries and hemorrhagic shock. Therefore, the use of adjuvant hemostatic dressings or devices and drugs to enhance blood-clotting capacity are essential to stop severe hemorrhage and prevent the death of injured Soldiers. Unlike noncompressible bleeding that has no prehospital remedy except the administration of a limited volume of fluid (Hextend) to treat hypotensive shock in the patient and possibly exacerbate bleeding, several advanced hemostatic products have been developed in the past 15 years for treating compressible hemorrhage. Some of these products were tested extensively in the laboratories, and a few selected products were deployed for use by US forces on the battlefield. This article reviews the physical properties, mechanisms of action, and risks and benefits of hemostatic agents/dressings that have been used on the battlefield. The efficacy and safety studies that led to selection of these agents and present deficiencies that must be addressed by new hemostatic products are also discussed.

HEMOSTATIC MECHANISMS OF TOPICAL AGENTS

There are essentially 2 mechanisms by which the topical hemostatic agents produce hemostasis when placed in bleeding wounds:

- Physically adhering to damaged tissues in the wound and sealing injured blood vessels to prevent further blood loss (eg, chitosan dressing).
- Accelerating and strengthening the clotting of blood present in the wound by incorporating into the developing clot and producing hemostasis. This mechanism is often achieved as a result of 2 related reactions: *a*) rapid absorption of water from blood in the wound which concentrates all clotting elements on the injured tissues, and *b*) a chemical reaction that activates the intrinsic coagulation pathway and platelets and promotes clot formation. Therefore, the activity of these products depends on the intact coagulation function of patients.

The majority of hemostatic agents, including gauze, facilitate hemostasis by the second mechanism. A few products with very high efficacy produce hemostasis by both mechanisms, such as WoundStat (TraumaCure, Bethesda, MD), a silicate-based mineral agent in granular form, and fibrin sealant dressing, a biological dressing made of plasma-derived clotting

proteins. Although the hemostatic efficacy of a topical agent has high importance, the agent's chemical effects on the exposed tissues and potential for causing greater damage in the wound or systemic complications must also be considered in the selection of an appropriate agent. There are other criteria that are uniquely important for the agents used in the military. Table 1 lists the properties of the ideal hemostatic dressing for tactical use, as recommended by a panel of military experts.

Table 1. Characteristics of the ideal hemostatic dressing for tactical applications.

Approved or cleared by the US Food and Drug Administration
Stops severe arterial and/or venous bleeding in 2 minutes or less
No toxicity or side effect
Causes no pain or thermal injury
Poses no risk to medics
Ready to use and requires little or no training
Durable and lightweight
Flexible enough to fit complex wounds and is easily removed without leaving residues
Stable and functional at extreme temperatures (-10 °C to +40 °C) for at least 2 weeks
Practical and easy to use under austere conditions (low visibility, rain, wind, etc)
Effective on junctional wounds not amenable by tourniquet
Long shelf life (> 2 years)
Inexpensive and cost-effective
Biodegradable and bioabsorbable

EARLY EFFORTS IN THE DEVELOPMENT OF HEMOSTATIC DRESSINGS

Until the onset of OEF and OIF, the Army Field Bandage (AFB) was the mainstay for controlling external bleeding. The AFB is composed of a thick layer of absorbent cotton wrapped in layers of gauze and attached to 2 long straps for wrapping around the wound. It absorbs large volumes of blood and provides a matrix that promotes platelet aggregation and blood coagulation while exerting pressure on the wound.

The early notion that up to a third of all combat deaths resulting from exsanguination could be prevented with the use of more effective hemorrhage methods⁴ focused the US Army's Combat Casualty Care Research Program on the development of more effective hemostatic products than gauze.



Figure 1. Topical hemostatic products deployed during Operations Enduring Freedom and Iraqi Freedom.

Dry Fibrin Sealant Dressing

Nearly a decade of collaborative research between the US Army and the American Red Cross with funding support by the Department of Defense resulted in the development in the laboratory of the first advanced hemostatic dressing that was significantly more efficacious than the AFB.¹⁶ The new product was developed for both prehospital and conventional surgical application. The dressing was the dry form of the existing hemostatic product known as liquid fibrin sealant used in routine surgical procedures. However, because liquid fibrin sealant preparation was complicated and time-consuming, it had no utility in trauma care. Dry fibrin sealant dressing (DFSD) (American Red Cross Holland Laboratory, Rockville, MD) was made of lyophilized clotting proteins purified from pooled human plasma from donated blood that was ready to use. Layers of fibrinogen and thrombin with calcium chloride were freeze-dried onto an absorbable backing material¹⁷ (Figure 1). Upon contact with blood, the proteins dissolved and the enzymatic reaction between thrombin and fibrinogen resulted in formation of a fibrin layer that adhered tightly to injured tissue and stopped the hemorrhage. In a complex wound, the dressing could be added as a powder that mixed with blood and accelerated the clotting reaction and strengthened the final clot. The efficacy of this dressing has been proven in a number of experimental models, including ballistic, extremity, and parenchymal injuries in normal and coagulopathic swine.¹⁸⁻²⁴

The main safety concern with this dressing was the risk of viral transmission (specifically hepatitis and human immunodeficiency virus) from the use of human clotting proteins purified from pooled plasma. This risk, however, has been virtually eliminated because of stringent screening of blood donors,

extensive testing of collected blood, and recent advanced methods of viral inactivation (solvent detergent and ultraviolet radiation) in plasma.¹⁷ Nevertheless, since the main components of DFSD are derived from plasma, it is considered biologic and, contrary to other hemostatic agents, must be tested for safety and efficacy in clinical trials to receive approval from the US Food and Drug Administration (FDA) for human use. Under an FDA-approved Investigational New Drug protocol, a number of DFSDs were deployed early to Iraq and Afghanistan for treating external hemorrhage in consenting Soldiers,²⁵ but were soon withdrawn due to deployment of a new dressing with presumably similar potency that had received FDA clearance (HemCon bandage, HemCon Medical Technologies, Inc, Portland, OR). Dry fibrin sealant dressing was used on only one injured Soldier, and it successfully stopped the arterial bleeding where all other attempts had been futile.²⁶

The necessary clinical trials required substantial funding which could not be secured at the time, therefore, further manufacturing and marketing efforts of this effective product were suspended in 2002. However, a renewed interest by larger companies may bring this potentially useful product to the clinics. At least one similar product, Fibrin Patch (Ethicon, Inc, Somerville, NJ), has completed phase I and phase II clinical trials* and the manufacturer is seeking FDA approval for future marketing.

Rapid Deployment Hemostat Bandage

The rapid deployment hemostat (RDH) dressing (Marine Polymer Technologies, Inc, Danvers MA), developed with funding support from the Office of Naval Research, is a chitin-based hemostatic dressing

*http://www.clinicaltrials.gov/ct2/results?spons=%22Ethicon%2C+Inc.%22&spons_ex=Y

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composed of poly-N-acetyl-glucosamine (fully acetylated), which is derived from marine microalgae. Although the mechanism of its hemostatic action remains unclear, suggested mechanisms include red blood cell aggregation, platelet activation, activation of the clotting cascade, and local vasoconstriction via endothelin release.²⁷⁻³⁰ The original RDH dressing showed the ability to control minor bleeding (3 mm deep splenic laceration) in normal and coagulopathic pigs,^{31,32} but was ineffective against severe arterial (aortotomy injury²²), venous (grade V liver injury³³), and mixed (femoral artery and vein transection) bleeding in the studies that were conducted in our laboratory and other locations.³⁴ Other investigators reported that the new generation of RDH dressings, modified RDH (mRDH) bandages, with an increase in active ingredient, was effective in aortic and liver injury models in swine.^{35,36} A small clinical study (10 patients) reported successful treatment of liver hemorrhage in coagulopathic patients with intracorporeal use of mRDH bandages.³⁷ This dressing has received FDA clearance as a class I medical device and is commercially available at the price of \$1,000 per dressing. There are no reported harmful effects associated with its use. This dressing has not yet been deployed to the combat theaters.

HemCon Bandage

As planning for OEF and OIF developed, research efforts by academia and industry were accelerated to produce other dressings/agents which were more effective than gauze, easier and less expensive to produce, and could be licensed without the need for clinical trials. The results were development of 2 new products, the HemCon (HC) bandage and QuikClot (QC) (Z-Medica Corp, Wallingford, CT) granules (Figure 1). The HC dressing was developed by the Oregon Medical Laser Center (Portland, OR) with some funding support by the US Army. The dressing is made of freeze-dried chitosan, a partially deacetylated form of chitin (a natural polysaccharide) found abundantly in shellfish such as shrimp. In small animal studies, liquid chitosan was shown to have hemostatic properties.^{38,39} The primary mechanism of HC hemostatic action appears to be strong adherence to wet tissues and sealing of the injured vessels.⁴⁰ In an early study, the prototype of HC was tested in our laboratory in a swine model with a grade V liver injury. The results demonstrated the superior efficacy of this dressing over regular gauze for controlling

venous bleeding.⁴⁰ However, in subsequent confirmatory studies in which the final product was tested in the same model, the differences between HC and gauze were less significant (A. E. Pusateri et al, unpublished data, March 2003).

The HC bandage received FDA clearance as a hemostatic device in 2002 and a few months later was distributed among US Army personnel for use in the treatment of external bleeding on the battlefield. The efficacy of this dressing was reexamined against arterial bleeding in more relevant swine models. The results showed that the adherence of HC to the damaged tissues/vessels decreases with time, and that even initially successful dressings (70%) cannot stop the bleeding for more than one hour after application.²⁴ In a groin injury model, this dressing was totally incapable of controlling arterial bleeding from the femoral artery injury.²³ Since the marketing of the original dressing, HemCon Company has made several modifications to the product to improve its efficacy and applicability. The new generations of HC are thinner and more flexible and conform better to the wounds. One version of this dressing, ChitoFlex, has a ribbon-rolled shape with no backing (both sides are active) which can be used for packing deep penetrating wounds. However, none of these changes has substantially increased the overall efficacy of this product in animal model testing. There have been no reports of allergic reaction or any other side effects associated with the use of this dressing in patients. Currently, the HC dressing is being replaced in the military with a simpler and presumably more effective dressing called Combat Gauze.

QuikClot

QuikClot (QC), the first mineral-based (zeolite) hemostatic agent, was introduced in open granular form (Figure 1). This product was also developed with funding support from the Office of Naval Research. The hemostatic mechanism of this agent was suggested to be the rapid water absorption concentrating all clotting proteins and cells in the wound.⁴¹ The interaction of water with zeolite, however, caused an exothermic reaction that generated significant heat in the wound and often caused burning injuries. The heat generation may have also contributed to the hemostatic function of QC. The efficacy of QC was primarily demonstrated in 2 studies using a swine model with a groin injury that

included complete transection of both the femoral artery and the vein and limited fluid resuscitation.^{34,42}

Treatment of this bleeding with QC resulted in a significantly higher survival rate (100%) compared to untreated animals (0% to 16%). Treatment of this wound with standard gauze alone also led to an approximately 60% survival rate. There were no significant differences in blood loss among groups. On the other hand, in a subsequent study in which QC was tested in our model of high-pressure arterial bleeding (6 mm femoral arteriotomy), it failed to provide hemostasis or improve survival rate, and was essentially no better than AFB.²³ In our liver injury model with venous bleeding, however, QC was more effective than regular gauze.⁴³

The safety of QC was a controversial issue. Burning injuries were quite evident on the skin, skeletal muscle, and blood vessels that were exposed to QC and included potentially irreversible damage to the femoral nerve.²³ The abscess and necrosis of skeletal muscle and femoral vessels treated with QC were also seen in a survival study in swine one week after treatment.⁴⁴ QuikClot received FDA clearance as a medical device without clinical testing, and, despite these safety concerns, it was widely distributed among US Marine and Navy personnel for treatment of external hemorrhage. The argument was that if QC could stop a life-threatening hemorrhage and save the life of a Warfighter, although in the process caused burning injuries, its benefits clearly outweighed its potential side effects. This argument seemed valid if indeed QC could stop a life-threatening hemorrhage, but the experimental evidence from some laboratories indicated otherwise.^{23,45} Nevertheless, anecdotal case reports of successful use of QC for treatment of injured troops supported its use in Iraq and Afghanistan.⁴¹ Similar successes regarding HC dressing use were also reported among the Army personnel.⁴⁶ A recent report by Rhee et al described the use of QC in 103 documented cases in civilian and military settings with only a few cases of significant tissue burning, one of which required a skin graft.⁴⁷ Tissue burning remained an issue that may have limited its use of QC in the field. Therefore, the manufacturer (Z-Medica) replaced the original QC zeolite granules with synthetic zeolite beads that produce minimum exothermic reaction⁴⁸ and packaged them in small porous cotton bags for easy application and removal (QuikClot ACS+) (Figure 1). The original QC is no longer produced or sold by the company.

DEVELOPMENT OF NEW HEMOSTATIC AGENTS/ DRESSINGS

Despite the positive anecdotal reports, other reports^{49,50} and information from combat medics implied limited use or avoidance of available hemostatic agents in the field because of either painful burning effects (QC) or poor efficacy in controlling severe bleeding (HC). Therefore, since deployment of QC and HC dressings, continuous research and development by industry has produced a number of new hemostatic products that were rapidly marketed as medical devices after receipt of FDA clearance. The clearance process was relatively simple; as long as the companies could prove that their products were equivalent to previously approved agents (ie, QC or HC dressing), they could market their products.

At least 10 to 12 new products entered the market, all of which were indicated for temporary control of external bleeding and were claimed to be safe (no thermal injury) and efficacious. Our laboratory and the Navy Research Group were tasked to conduct large animal studies to identify more efficacious products beneficial for military applications. After a few products were eliminated in preliminary screening tests, the more promising new agents were tested in 3 models of extremity injury that involved complete transection of the femoral artery and the vein, 4 mm femoral artery punch with limited fluid resuscitation^{51,52} and 6 mm femoral artery punch and unlimited fluid resuscitation.^{53,54} The results reported by both laboratories were surprisingly consistent with one exception: the QuikClot ACS+ showed higher efficacy than average in the Navy studies, but was not different from the HC dressing (control treatment) in our study.

The top 3 agents were WoundStat, Combat Gauze (Z-Medica Corp, Wallingford, CT), and Celox (MedTrade Products Ltd, Crewe, UK) (Figure 2), which were significantly more effective in reducing blood loss and improving survival than the control dressing (HC) and QC, and had no immediately apparent side effects (Figure 3). Based on the overall results, the efficacy of these 3 agents could be ranked in the order (1) WoundStat, (2) Combat Gauze, (3) Celox. However, the differences in blood loss or survival rates were not statistically significant among the agents. The 3 agents are further discussed below. Information about other agents tested is found in earlier publications.⁵¹⁻⁵⁴

Evaluation of Topical Hemostatic Agents for Combat Wound Treatment

WoundStat

WoundStat (WS), another mineral-based granular agent, consists of smectite minerals and is a nonmetallic clay made of sodium, calcium, and aluminum silicates. When exposed to water or blood, WS granules absorb water and form a clay material with high plasticity that, upon compression, binds tightly to underlying tissues and seals the bleeding sites. In addition to water absorption, which concentrates clotting factors, the granules have negative electrostatic charges that activate the intrinsic clotting cascade and accelerate the blood-clotting process.⁴⁵ The mineral is not biodegradable and therefore must be removed entirely from the wound site before definitive surgical repair is done. The tissue adhesiveness of this clay, along with its potent clotting ability, secured hemostasis in all the experiments and led to 100% survival of pigs.^{45,53} Only 10% of animals treated with the HC dressing as control agent survived the experiments.⁵²

Mixing WS granules with water did not generate heat and caused no thermal damage, however, there were other findings in the tissues that were safety concerns. For example, although applying and covering the wound with this agent was relatively easy, eventual removal of the clay material from the wound was cumbersome and required extensive irrigation and debridement. Despite these efforts, microscopic WS residues were found in the lumen of the majority of treated blood vessels.⁵³ Given the strong clotting activity of WS granules, these residues could become the source of local or systemic thrombosis if blood flow were reestablished in the treated vessel. These anomalies and other changes in treated vessels led to the design of an experimental study to evaluate the safety of WS treatment, even though the agent had already been approved by the FDA for clinical use.⁵⁵ The result is described later in the section, WoundStat and Combat Gauze Safety Studies.

Combat Gauze

Combat Gauze (CG) may be considered the first mineral-based hemostatic dressing. This dressing is a 4-yard-long, 3-inch-wide roll of nonwoven surgical gauze made of 50% polyester and 50% rayon impregnated with kaolin, an aluminum silicate mineral. Kaolin is a potent activator of contact (intrinsic) clotting pathway that accelerates the initial

onset and speed of clot formation. CG was the most effective dressing tested in our arterial hemorrhage model and resulted in 80% survival of the animals.⁵⁴ However, unlike the adhesive products, this dressing often does not provide immediate hemostasis when applied over wounds, resulting in more blood loss than other agents. Hemostasis is eventually achieved when a hemostatic clot is formed in conjunction with CG on the injury site. Unlike the granular agents, application and removal of CG are easily accomplished and require no special procedures. Because the hemostatic function of CG depends solely on the blood-clotting activity of hosts, this dressing may be found to be less effective in patients with coagulopathy.

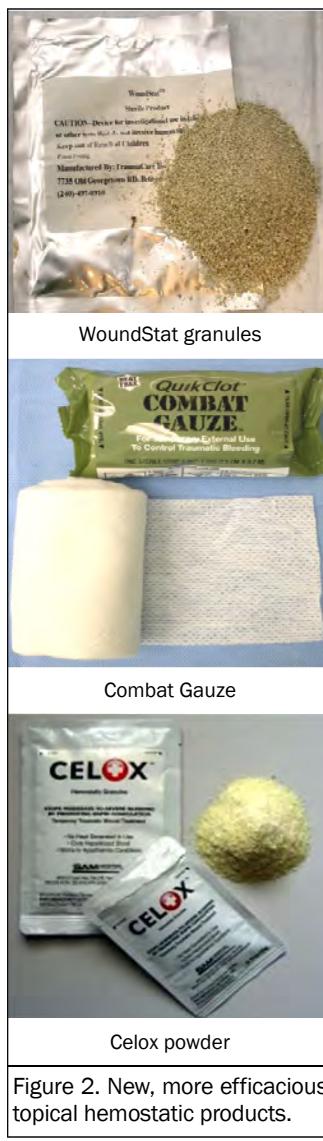


Figure 2. New, more efficacious topical hemostatic products.

Celox

Celox (CX) is a chitosan-based hemostatic agent in granular form containing a proprietary blend of different chitosan compounds. The chitosan particles are positively charged, binding with negatively charged surfaces such as red blood cells and platelets. The he-

mostatic mechanism of CX is mediated by a mixture of chemical and mechanical (adherence) linkages to red blood cells and tissues, forming a physical barrier around the severed vessels. Treatment of the arterial hemorrhage with CX in our model resulted in an approximately 50% reduction in blood loss and 60% survival rate of tested animals.⁵³ It was also shown to be more effective than QC and HC dressing in a groin injury model involving transection of femoral vessels.⁵⁶ The hemostatic activity of CX was inconsistent (all or none) in our experiments, but in successful cases, hemostasis was much more stable than using other chitosan products (HC).

Although in principle chitosan is a bioabsorbable material, CX hemostatic powder is not considered bioabsorbable and therefore must be removed from the wound prior to surgical repair. Since it forms large clumps when wetted with blood, removal of CX from wounds is much easier than other granular/powder agents (ie, WS and QC). The in vitro blood tests (thrombelastography) also showed that CX (chitosan) particles do not affect the clotting activity of blood. The possible CX residues in the wound are likely to be degraded, causing no thrombotic complications. CX elicits stronger inflammatory reaction than other hemostatic products, but otherwise appears to be a safe agent. Some civilian first responders and a few military units are carrying CX for treating hemorrhage, however, the light powder nature of this agent, which is more difficult to apply in the field (especially in the low-visibility or windy conditions), has discouraged wide distribution and use of this agent on the battlefield. Attempts by the company to package this hemostatic powder in dissolvable bags for easier application have not been successful because of the loss of hemostatic activity.⁵⁴ The CX as powder can be applied to deep penetrating wounds by a new syringe delivery system.

SAFETY EVALUATION OF HEMOSTATIC AGENTS

All the above-mentioned hemostatic products except DFSD have been recognized as Class I medical devices by the FDA and have received marketing clearance by proving that the new products are equivalent to similar agents (ie, QC) that were cleared by the FDA after 1976.⁵⁷ This pathway also requires some standard safety testing, including in vitro cytotoxicity using fibroblast cell culture and in vivo sensitivity, irritability, and systemic toxicity, all of

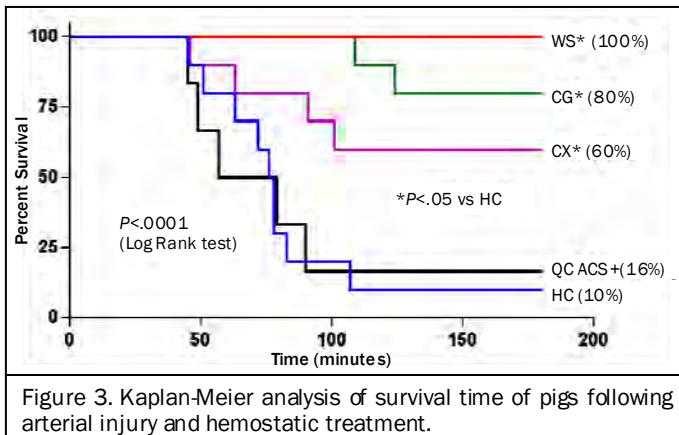


Figure 3. Kaplan-Meier analysis of survival time of pigs following arterial injury and hemostatic treatment.

WS - WoundStat; CG - Combat Gauze; CX - Celox; QC - QuikClot ; HC - HemCon

which are done in small animals (rats and rabbits). These tests evaluate the potentially adverse effects of chemicals that may be eluted or extracted from a medical device. Although no reaction may indicate that a material is free of harmful extractable, it is certainly not evidence that the device is fully biocompatible and safe for applying over an external wound with access to systemic circulation. Considering that hemostatic devices are intended to stop bleeding from vascular injuries, it is likely that they will come in direct contact with endothelial cells in the injured vessels and inflammatory cells drawn to the site of injury. Therefore, the standard safety tests applied to most medical devices may be inadequate in evaluating hemostatic agents, particularly those with hemostatic minerals. This inadequacy was never more apparent than in the case of the original QC. Although none of the standard tests showed that the zeolite itself or its eluted chemicals are harmful, a simple test of pouring QC granules into a beaker containing blood would have revealed the extreme rise of temperature and its potential burning injury when it is applied to the wound.

WOUNDSTAT AND COMBAT GAUZE SAFETY STUDIES

For the reasons explained above (histological evidence), it was suspected that these hemostatic agents, particularly WS, may have potential thrombogenic effects when applied to wounds with major vascular injuries. To test this hypothesis, we developed a new wound model in swine that would demonstrate the effect of these agents locally as well as detecting any systemic embolism.⁵⁵ The wound involved partial transection of the carotid artery and jugular vein in the neck and was treated with either

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WS or CG to control hemorrhage for 2 hours. The control wounds were treated with regular gauze. Following treatment, the hemostatic agents were removed, wounds debrided extensively, vessels repaired by suturing, and blood flow reestablished in the vessels for 2 hours.

Computed tomography (CT) angiography and direct observation afterwards showed that the majority of vessels treated with WS were occluded with large thrombi/clots, whereas no abnormality was seen in gauze- or CG-treated vessels (Figure 4). Granules of WS and blood clots were also found in the lung of one pig. Histological examination revealed significant endothelial and transmural damages in the WS-treated vessels. Microscopic residues of WS that were associated with arterial thrombosis were also found in the lung. The histological changes of gauze and CG treatment were similar and mild.

A follow-up *in vitro* study⁵⁸ using human endothelial and mouse macrophage-like cells substantiated the *in vivo* findings and showed severe toxic necrosis of the cells after direct exposure to WS minerals. However, epithelial HeLa cells were unaffected by WS. These *in vivo* and *in vitro* findings, along with the results of another safety study by US Air Force scientists,⁵⁹

resulted in rapid suspension of WS distribution and permanent withdrawal of this hemostatic agent from the US military medical practice. To our knowledge, this product was not used on any of our casualties during the brief period that it was deployed.

To ensure that CG with kaolin has no long-term detrimental effect on the wound, the dressing was also tested in a survival swine study using the same wound model. CT images showed patency and normal blood flow in the treated vessels of all animals 2 weeks after surgery. Histologically, healing progressions of wounds and vessel walls were similar to those of the control group (gauze treated) with normal endothelium (thrombus-free) present in all vessels (B.S.K., unpublished data, 2009). Because of high efficacy, ease of use, and proven safety, CG was recommended by the Tactical Combat Casualty Care Committee for distribution among US forces for use as the first line of treatment of external hemorrhage on the battlefield refractory to tourniquets. It has essentially replaced the previously deployed hemostatic agents (HC and QC). The initial anecdotal reports of uses of CG on the battlefield are very positive and encouraging. The properties of the new hemostatic agents are compared to those of the older products in Table 2.

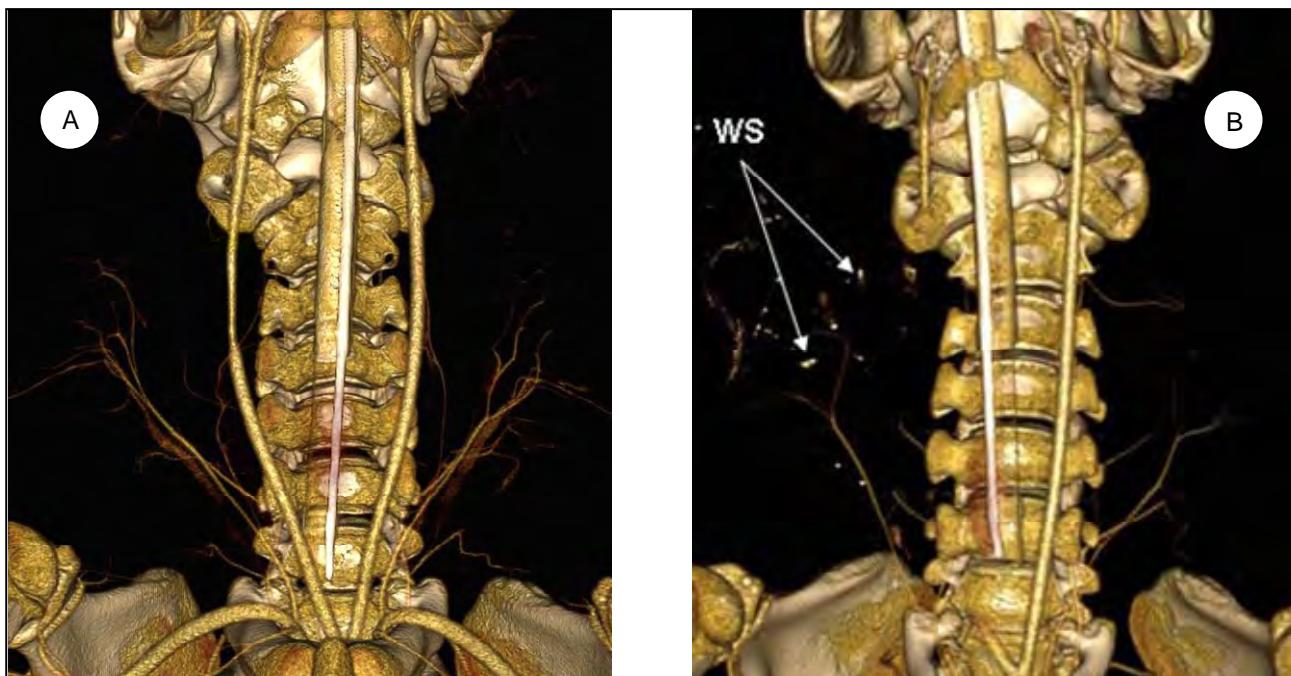


Figure 4. Computed tomography images of pigs' left (intact) and right carotid arteries treated with Combat Gauze (A) and WoundStat (B) 2 hours after blood reflow. WS indicates WoundStat. Reproduced from Kheirabadi et al⁵⁵ with permission.

CURRENT DEFICIENCIES IN THE TREATMENT OF COMPRESSIBLE BLEEDING

Nearly all hemostatic agents are adjuvant to the patient's own blood clotting activities. In general, these agents physically obstruct (decrease) the outflow of blood in the wound, accelerate clotting reactions, and provide a matrix for increased platelet interactions, resulting in faster and stronger fibrin clot formation that can bind to and seal vascular injuries. Therefore, the effectiveness of these agents depends heavily on the competent coagulation function of patients. In the combat environment, trauma and hemorrhage caused by explosion (massive tissue injuries), resuscitation with a synthetic colloid fluid (hemodilution), delayed evacuation and transport in helicopters (hypothermia), and hypovolemic shock (metabolic acidosis) have collectively created conditions that can induce early coagulopathy in some casualties. Among the combat casualties who required blood transfusion, over one-third (38%) were diagnosed with acute traumatic coagulopathy with an international normalized ratio (INR) of 1.5 or more upon arrival at a combat support hospital. High mortality (24%) was associated with early coagulopathy and acidosis in these patients.⁶⁰ A diffuse large area of bleeding associated with multiple vascular injuries in coagulopathic patients is much harder to treat with ordinary hemostatic agents than defined bleeding in noncoagulopathic patients.

We tested the efficacy of the 2 most powerful hemostatic products, WS and CG, to control bleeding in coagulopathic swine.⁶¹ The mineral components of these agents (smectite and kaolin, respectively) were found to be potent activators of the intrinsic clotting cascade, promoting faster and stronger clot formation when added to native blood.^{53,54} The additional sealant properties of WS clay when mixed with blood suggested an advantage for the treatment of coagulopathic bleeding that may not be possible with other hemostatic agents. Some *in vitro* data also supported this hypothesis,^{62,63} therefore, it was tested in another large-animal study.⁶¹

Coagulopathy was induced in pigs prior to injury by removal of 50% of their circulating blood volume and replacing it with an equal volume of isotonic Hextend solution (hemodilution) and lowering their normal body

temperature by 5°C ($\approx 34^\circ\text{C}$, hypothermia), resulting in an INR of 1.4. The pigs were then subjected to the same femoral artery injury as before and treated with WS or CG. Regular gauze was used as control treatment, and a new fibrin sealant dressing (FAST bandage) was also added to the study. Although the arterial bleeding in this model did not mimic a typical coagulopathic bleeding, it provided a standard condition for testing these agents under coagulopathic state, which could be directly compared with the previous results in normal animals. The results showed that WS and CG were generally unable to stop the bleeding in the coagulopathic animals. This was expected for CG with 40% survival rate but was unexpected for WS with only 13% survival rate because of its tissue sealant properties. Apparently, the tissue adherence of WS is mediated by clot formation, and this property is lost with preexisting coagulation deficiency.

There is a need for a new class of hemostatic agent that can function independently of host coagulation function and stop bleeding in coagulopathic patients. Such a product will be particularly beneficial to casualties who develop early coagulopathy at the point of injury. The most successful product in our coagulopathic hemorrhage models has been the fibrinogen-based dressings.^{21,56,65} These dressings deliver the main components of blood clots, including fibrinogen, thrombin, CaCl₂, Factor XIII, and other proteins, to the wound and form strong hemostatic fibrin clots bypassing the patients' own clotting

Table 2. Comparison of characteristics of available hemostatic agents.

Characteristic	Hemostatic Agents				
	QC ACS ⁺	HemCon	Celox	WoundStat	Combat Gauze
Hemostatic efficacy	+	+	+++	++++	++++
Side effects	No	No	No	Yes	No
Ready to use	Yes	Yes	Yes	Yes	Yes
Training requirement	+	+	+	+++	++
Lightweight, durable	+	+++	+++	+	+++
2-yr shelf life	Yes	Yes	Yes	Yes	Yes
Stable in extreme conditions	Yes	Yes	Yes	Yes	Yes
Cleared by FDA	Yes	Yes	Yes	Yes	Yes
Biodegradable	No	No	Yes	No	No
Cost (\$)	≈30	≈75	≈25	≈30	≈25

NOTE: A single + symbol indicates an agent has met the minimum requirement. Multiple + symbols indicate degree of exceeding the minimum requirement.

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functions. The missing platelet component is compensated by the high fibrinogen content of the dressing that increases fibrinogen concentration in the wound more than a factor of 10 above normal. Moreover, because of its biological nature, the fibrinogen-based dressings are fully absorbable and can be implanted permanently to control some refractory bleedings in patients. The dressing can also potentially eliminate the cleansing surgeries in damage control operations that are necessary for removing gauze and other nonabsorbable hemostatic materials used to control hemorrhage and secure hemostasis. At least 2 such dressings (FAST and Fibrin Patch) are being developed in the United States and are undergoing clinical trials to receive FDA approval for future use.

There are other situations in which treatment of some external wounds might also be difficult, if not impossible, with available hemostatic agents. An example is junctional wounds that involve amputation of extremities at the groin or shoulder levels. These wounds are large with profuse bleedings, which, if not controlled promptly, will cause the victim to exsanguinate in a short time. A tourniquet, perhaps the most effective hemostatic device, is ineffective (cannot be applied properly) to control the hemorrhage because of the location of the injury. Other hemostatic dressings are also no match for these types of wounds and hemorrhage. A mechanical device (adjustable clamp) has been developed (and recently received FDA clearance) to exert constant and high pressure on proximal regions and occlude main feeding vessels (iliac and subclavian arteries) to slow down the bleeding. Large-surface-area dressings that are coated with different hemostatic agents with long wrapping strips are also being produced to be used alone or in conjunction with mechanical devices.

CONCLUSION

Future combat scenarios in which troops will be more dispersed imply that evacuation times of casualties may exceed 24 hours. Even in urban environments, evacuation may be delayed significantly, as was experienced in Somalia.⁶⁵ The implication is that at a minimum, several hours may pass before any surgical intervention is possible to treat injured Soldiers, and it is well established that mortality rates will rise with increasing evacuation times.⁶⁶ Since the introduction

of the Army field bandage, significant progress has been made in the past decade toward developing new hemostatic products for treating external wounds. The new dressing, Combat Gauze, offers the simplicity and convenience of regular gauze, enhanced by a potent hemostatic mineral (kaolin) that together stop the majority of compressible bleeding in noncoagulopathic patients. Development of even more efficacious products (ie, chitosan-based gauze dressings) continues, but the greatest need for controlling bleeding on the battlefield centers around noncompressible torso wounds.¹⁵ Other targets are control of bleeding in coagulopathic patients in prehospital and hospital settings after significant blood loss and fluid resuscitation. Future fibrinogen-based dressings may offer the best chance for stopping these types of bleeding.

Our responsibilities are to:

1. Publicize these unresolved problems and challenge scientific communities to propose new and practical solutions.
2. Support and collaborate with research and development efforts that may resolve these medical problems.
3. Conduct independent, unbiased research to assess the true safety and efficacy of newly developed products.
4. Determine their relevance and potential benefit in combat casualty care, thereby ensuring that the best available treatments for control of hemorrhage are rendered to our Soldiers.

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New Tourniquet Device Concepts for Battlefield Hemorrhage Control

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ABSTRACT

Background: Given the recent success of emergency tourniquets, limb exsanguination is no longer the most common cause of preventable death on the battlefield; hemorrhage amenable to truncal tourniquets now is. The purpose of the present study is to discuss the gaps today in battlefield hemorrhage control and candidate solutions in order to stimulate the advancement of prehospital combat casualty care.

Methods: A literature review, a market survey of candidate devices, a request for devices, and an analysis of the current situation regarding battlefield hemorrhage control were performed.

Results: Hemorrhage control for wounds in the junction between the trunk and the limbs and neck is a care gap in the current war, and, of these, the pelvic (including buttock and groin proximal to the inguinal ligament) area is the most common. Historical and recent reports give background information indicating that truncal tourniquets are plausible devices for controlling junctional hemorrhage on the battlefield. A request for candidate devices yielded few prototypes, only one of which was approved by the US Food and Drug Administration.

Conclusions: In order to solve the now most common cause of preventable death on the battlefield, junctional hemorrhage from the pelvic area, the planned approach is a systematic review of research, device and model development, and the fielding of a good device with appropriate training and doctrine.

INTRODUCTION

In the bestselling nonfiction book and popular movie, *Black Hawk Down*,¹ Corporal James “Jaimie” Smith died of a gunshot wound and groin hemorrhage that was too proximal for a tourniquet.² His wound was at the junction between his trunk and thigh just beyond his body armor. This type of junctional injury has become more common recently, partly due to better body armor. With the success of regular tourniquets in the current war, isolated limb exsanguination is no longer the most common cause of preventable death on the battlefield; hemorrhage amenable to truncal tourniquets now is most common.^{3,4} Groin hemorrhage is the most common type of junctional bleeding where regular tourniquets cannot work.⁵ Pressure point control of hemorrhage in the groin and limbs where collateral blood flow is present has been called a “euphemistic misnomer” by investigators because blood flow is restored momentarily in normal volunteers.⁶ The Committee on Tactical Combat Casualty

Care recommended military antishock trousers for hemorrhage control about the pelvic body region,⁷ but effectiveness is poor, and contraindications are numerous.⁸⁻¹³ Therefore, in 2009, the Committee made truncal tourniquets a research priority. Soon thereafter, the Combat Casualty Care Research Program of the US Army Medical Research and Materiel Command requested candidate devices in order to address junctional bleeding. Of the few candidate devices provided, only one as of this writing, the Combat Ready Clamp (Combat Medical Systems, Fayetteville, NC) was approved by the US Food and Drug Administration. An update on the newest challenges of combat casualty care now needs explicit fills of specific knowledge gaps, especially on delineation among the “knowns and unknowns” of practical hemorrhage control measures. For example, only 3 devices are evidenced to be lifesaving for extremity injured casualties: emergency tourniquets, Thomas’ splint, and pelvic binders. The purpose of the present review is to discuss today’s gaps in battlefield hemorrhage control

and candidate solutions in order to stimulate the advancement of prehospital combat casualty care.

JUNCTIONAL HEMORRHAGE CONTROL: AN IMPORTANT HEALTH CARE GAP ON TODAY'S BATTLEFIELD

We use the term “junctional” to include the groin proximal to the inguinal ligament, the buttocks, the gluteal and pelvic areas, the perineum, the axilla and shoulder girdle, and the base of the neck. We simply grouped these into a succinct label as they were at the junctions of the trunk. We use this label to discuss problem-solving. The lethality of limb injuries is less than junctional areas as hemorrhage is less and slower, and so the junctional hemorrhage control challenge is greater than in the limbs.¹⁴

Traumatic hemorrhage is a common, well recognized, and lethal problem in civilian and military settings for which numerous countermeasures have been recommended, and a few of which are evidenced to be lifesaving.^{2-5,7} A major goal in caring for such casualties is to stop the bleeding promptly as the main cause of death is hemorrhagic shock.¹⁵⁻¹⁹ Exsanguination-related mortality associated with major trauma has been noted to be unacceptably high,²⁰ especially when casualties receive nontherapeutic procedures such as laparotomy without arresting pelvic hemorrhage.²¹ Early trauma care is error-prone even in mature trauma systems, as delayed control of hemorrhage can lead to preventable deaths for which remedies can be effectively targeted.²² Delayed control of hemorrhage, notably pelvic, was the leading error in one study; most of these errors were early in care as clinical data were often incorrectly perceived or the provider formed an incorrect intent and performed a wrong action.²² Comprehensive and integrated health care is optimal when it includes the multiple essentials to best care, which may include use of algorithms, checklists, and protocols.²² Prompt diagnosis and comprehensive treatment are essential to an optimal survival rate in multiple injury casualties where damage control is effective and safe when well executed.^{16,23} Although many recent advancements have been hospital-based, most trauma deaths occur prehospital. This is especially so on the battlefield, and prehospital advancement is our focus in this review. Continued developments in prehospital care may improve survival by early hemorrhage control allowing better resuscitation.¹⁹ Additional importance of junctional hemorrhage control is due to the frequency of such bleeding in the current war.

JUNCTIONAL BLEEDING, COMMON ON TODAY'S BATTLEFIELD

Epidemiologically, we can estimate the number of casualties who might need a junctional hemorrhage control device in order to count the possible lives saved during the current war. During the current war, from October 1, 2001, to April 30, 2010, 6450 coalition casualties died, averaging 63 deaths per month.²⁴ According to the most recent report of the causes of death in casualties during the current war, only 23% (232/982) were “potentially survivable,” the rest had severe bodily disruption that was not survivable.⁵ Of these 23%, 20% had junctional injury and bleeding as a cause of death. Therefore, if all these 4.6% (20% of 23%) of casualties were savable with a device, then the maximum average monthly yield of optimal use of the device would be 3 casualties saved (4.6% of 63 per month). The rates of junctional hemorrhage is not clear in part because the words, categorization, and coding are yet to be adopted widely. For example, epidemiologically speaking, it is only possible at the moment to estimate that junctional hemorrhage from the lower extremity appears less common than the upper extremity perhaps because of the greater body surface area exposed to penetrating trauma in war. Clearly, there remain several important knowledge gaps regarding the rates of these lethal injuries.

A recent review of battle casualties that died of wounds indicated that 21% of cases had junctional bleeding possibly amenable to a truncal tourniquet.²⁵ A recent presentation of a review of US battlefield casualty data indicated that pelvic trauma deaths included 44% with a pelvic arterial injury.²⁶ The distribution of body regions injured in the current war are different than in previous wars by an increase in the regions not protected by body armor; the difference is likely related to more explosions now.²⁷ Explosions account for over 75% of all combat casualties, and their severity coupled with thoraco-abdominal protection by body armor has resulted in more severe orthopaedic injuries.²⁸ Orthopaedic trauma cases presenting with shock which can be refractory to resuscitation. Junctional lesions such as the superior gluteal artery hemorrhage can be difficult to control.²⁹ In a study of war casualties with penetrating gluteal injuries, surgeons noted that associated vascular injuries were present in 21% of cases, and overall, 76% required surgical management, with 14% developing postoperative complications. Transfusion requirements

were high, length of stays were long, and associated injuries to local structures were common.³⁰

Further evidence that junctional hemorrhage control is common comes from the weekly global video teleconference on war care. Recent casualties had 15% to 33% with junctional bleeding.* At the US Department of Defense Tourniquet Summit in 2010 in Stafford, Virginia, US Army Special Operations Command personnel gave a presentation on the need for a junctional hemorrhage control device on the battlefield today.

Although the need for hemorrhage control in junctional body regions is now common, the challenge to control that bleeding is difficult.

HEMORRHAGE CONTROL CHALLENGE: LARGE ARTERY LESIONS WITH JUNCTIONAL BLEEDING

Numerous aspects of vessel lesions affect hemorrhage. Arterial lesions are generally more lethal than venous lesions, and higher arterial pressure can cause more rapid loss of blood volumes.³¹ Normal blood flow in vessels such as an artery is related to the fourth power of the radius, and so larger, proximal vessels such as in the groin or axilla therefore have greater arterial blood flow than distal limb arteries. Normal blood flow is proportional to the fourth power of the vessel radius (Poiseuille's law: $Q=(\Delta P\pi r^4)/(8\eta l)$, where Q is the volumetric blood flow rate; ΔP is the driving pressure drop; π is the mathematical constant, approximately 3.14159; r is the vessel radius; η is the dynamic viscosity; and l is the length of the vessel).³² Blood loss is also faster in larger than in smaller vessels. Proximal arterial lesions are more lethal than distal ones, probably because greater vessel caliber at a higher pressure permits larger volume and more rapid blood loss.^{14,33} Hemorrhage rate from a vessel leak is estimated by a derivation of Bernoulli's equation: $Q=A\sqrt{[(2\Delta P)/(\rho+v^2)]}$, where the hemorrhage rate (Q) is the laceration area (A) times the square root of twice the transmural pressure change (ΔP) divided by the blood density (ρ) plus the velocity (v) squared.^{32,34-39} Passive vessel wall tension can increase arterotomy area (size of the lesion opening in the artery wall) and the hemorrhage rate or volume. Active wall tension from smooth muscle contraction can further increase opening size and thereby worsen hemorrhage. Further, casualty movement, such as limb movement, may lead

to tissue translations, clot shear, plug disruption, and rebleeding which have been directly observed in animal models of hemorrhage and hemorrhage control.⁴⁰

Mathematical or medical bioengineering models of compressible tube phenomena need more practical applications, not just theoretical development.⁴¹ The science of collapsible tubes such as arteries has only been partly worked out, and some applications to hemorrhage control problems indicate compression may be helpful, but the works are preliminary or limited.⁴² Although some of these principles of transmural pressure gradients perhaps controlling bleeding have been described and seem plausible, their application to control traumatic hemorrhage control is incomplete in clinical care. The ideas are promising, but the specific mechanisms and applications have not been evidenced to be effective or simple.

Given a growing understanding of the challenge of junctional hemorrhage control, candidate solutions have been proposed.

CANDIDATE SOLUTIONS TO CONTROL JUNCTIONAL HEMORRHAGE

Many candidates exist to control junctional hemorrhage, but few are likely to be practical in the near term. Damage control such as emergency room thoracotomy and aortic clamping or simple ligation of major vessel injury can save casualties with critical injuries from exsanguination, but these solutions are in a hospital setting.⁴³⁻⁴⁵ Direct pelvic packing is gaining in popularity, but evidence is preliminary and also hospital-based.⁴⁶ Particularly, application of damage control principles to prehospital settings has been difficult. Selective angiographic embolization is safe and effective to control refractory, life-threatening bleeding, but this intervention is hospital-based.^{47,48} Use of a clinical algorithm including diagnostic radiology, external skeletal fixation of pelvic fractures, and early angiographic embolization was effective and safe to rapidly control hemorrhage in hemodynamically unstable trauma patients, but these interventions were hospital-based specialty services.^{49,50} Similarly, hospital-based surgical interventions have included saline-filled Penrose drains for hepatic injury hemorrhage control and Foley urinary catheter use for hemorrhage tamponade. Extravascular balloon cathe-

*General data range summarized from the Joint Theater Trauma System weekly worldwide video teleconferences over the period July 22 through August 18, 2010.

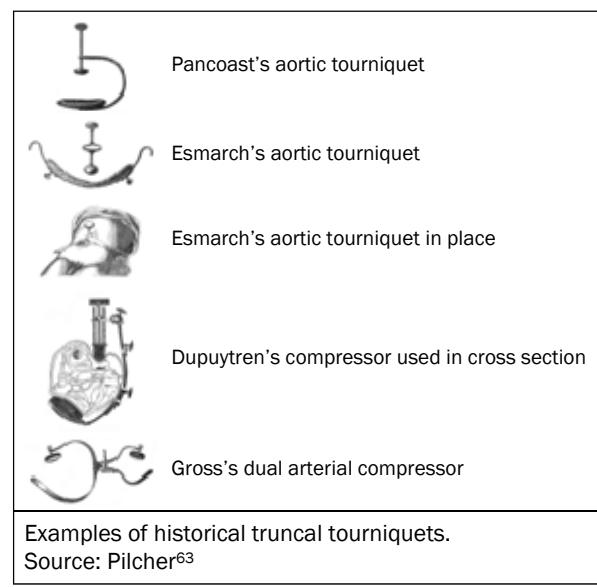
ters inserted into hemorrhaging wounds can control bleeding, but the wound-balloon interface should conform for best tamponade.⁵¹ A balloon-based device inserted into a deep, penetrating wound and inflated quickly to stop bleeding is analogous to that with which experienced clinicians may be familiar: balloons inserted into the esophagus or stomach to control internal hemorrhage from esophageal varices. However, rarely are war wounds esophagus-shaped. The main challenge today is big, open, bleeding war wounds from explosions, not tunnel-like, contained wounds which may be seen more with lower velocity gunshots or civilian wounds. Along the tamponade idea, iatrogenic abdominal cavity insufflation has decreased blood loss and improved hemodynamics in a pig model of traumatic venous hemorrhage, so iatrogenic abdominal insufflation may be a plausible candidate for prehospital care of abdominal injury. However, there are numerous physiologic risks, and the benefits may be limited to controlling venous bleeding.⁴³ Pelvic binders or circumferential compression devices in early care of patients with unstable pelvic fractures appear effective, but indicated fracture patterns are few while other patterns are contraindicated. A pelvic binder can reduce so called “open book” pelvic ring fractures, but they can over-compress and displace the fractures into the pelvic cavity in certain types of fracture patterns as lateral compression patterns are contraindicated.⁵² Thus, binder use is decided after radiographic interpretation of the fracture pattern and is not first aid. However, prospective data concerning mortality and complications is limited.⁵³ One review found that early emergency medical care with pelvic binders reduced neither hemorrhage nor mortality.⁵⁴ Another study found that in certain fracture patterns, expert use in a trauma system was associated with improved survival, less transfusion requirements, and shorter length of hospital stay.⁵⁵ A survey of hemostatic wound dressing use on the battlefield indicated that dressings were reported to be most useful on areas where tourniquets could not be applied to control bleeding, while they were most difficult to use in extremity injuries where they could not be placed easily onto or into the wounds.⁴⁶ Recent animal experiments showed life-saving efficacy in ideal circumstances in controlled, reproducible models, but human lifesaving effectiveness (as opposed to controlling hemorrhage) has not been evidenced, perhaps because adequate data are rarely collected, and the circumstances of use are naturally haphazard and uncontrolled.⁵⁶⁻⁵⁸

Military antishock trousers were used for hemorrhage control about the pelvic body region,⁷ but effectiveness is poor, and contraindications are numerous.^{8-13,59-61} Along a similar line of thought as pneumatic garments is abdominal insufflation of air, but currently this experimental idea has no direct prehospital data.⁶¹

There are many candidates for controlling junctional hemorrhage, of which many are currently unevidenced, but some may show promise for specific lesions, certain settings, or specialists.

HISTORICAL HEMORRHAGE CONTROL DEVICES USED FOR JUNCTIONAL BLEEDING

Historically, several surgeons have reported using truncal tourniquets or compression devices on large arteries like the common iliac in order to control hemorrhage and blood flow to the lower extremity or pelvis. Such devices have included several designs, such as those shown in the Figure. Pancoast's aortic tourniquet had a screw and counterpressure pad connected by a bar, and was similar to Lister's device, which was developed nearly simultaneously and independently.^{62,63} Esmarch's bandage, Dupuytren's compressor, and other devices worked in a similar manner by compression of the skin and underlying tissues to indirectly compress large vessels like the common iliac artery.⁶² These tourniquets were asymmetric in design, in that their compression was different than the circumferential tourniquet bands used in the limbs. Asymmetric tourniquets were aimed to specifically compress the arteries preferentially, rather



than all tissues like the symmetric tourniquets. Historically, the asymmetric tourniquets occluded arteries by pressure point compression while intending to permit collateral circulation.⁶² These asymmetric devices were difficult to position correctly, required anatomic knowledge, were difficult to maintain in position, were unreliable (particularly when users were inexperienced), and were eventually abandoned.² Petit's tourniquet worked well as an asymmetric design, probably because it had a large mechanical advantage. It was positioned by an expert surgeon, and the casualty did not move during surgery; but it too was eventually abandoned. Evidence indicates that tourniquets have been used before in truncal or junctional areas to control hemorrhage during surgery with at least temporary success in expert hands.^{62,63} Given the historical track record, it may now be plausible to make a junctional tourniquet which will control hemorrhage if used correctly.

An important point in the historical track record is that the expert hands were surgeons who had a detailed understanding of the arterial anatomy from a clinical perspective which probably helped them, but made it difficult for nonexperts with less anatomical knowledge to reproduce results.

ANATOMIC AREAS OF POSSIBLE PRESSURE POINT COMPRESSION IN HEMORRHAGE CONTROL

Collateral flow to the limb can lessen ischemia-reperfusion to tissues distant to bleeding. Therefore, if collateral flow can be maintained concurrently with hemorrhage control, effectiveness may be safe. However, if collateral flow permits retrograde blood to exsanguinate from the wound, then compression is ineffective. To find compression points without collateral arteries, surgeons and investigators have determined that the common iliac artery and its internal and external branches are a possible area.⁶⁴ Hemorrhage control at this area has included ligation or embolization of the internal iliac artery, sometimes bilaterally.¹⁶ In the supine position, the most common casualty position for routine assessment and transportation, the common iliac artery and aortic bifurcation are near the underlying bony structures on which a device may compress the artery closed. Here these arteries are compressible against the posterior vertebral bones. In computerized tomographic scans in US casualties with junctional bleeding, the distance from the aortic bifurcation to the fifth lumbar vertebral

bone endplate is 1.1 cm; the bifurcation is near midline. The inverted-Y configuration of the common iliac branches (left and right) has its center posterior to the umbilicus, the "belly button," a skin landmark offering a simple point at which to place the device. The common iliac artery courses over the body of the first sacral (S1) vertebral bone, which lies at the opening of the bony pelvic ring. The area to compress is about 7 cm long for each common iliac artery, so compression may be effective in about 14 cm. Compression of either common iliac artery stops the pulse in the same sided limb, and not the other side.

Therefore, there are adequate anatomic grounds on which to design a system for hemorrhage control based on pressure point compression in the pelvic area. A consideration of the physiology follows.

PHYSIOLOGIC BASIS OF CONTROLLING JUNCTIONAL BLOOD FLOW BY COMPRESSION

The physiology of aortic and common iliac artery compression has been studied in normal volunteers, and compression has shown effective control of blood flow to the distal extremities.⁶⁴ Investigators at the Medical College of Georgia modeled control of hemorrhage in critical femoral or inguinal penetrating wounds in an ultrasound evaluation.⁶⁴ The investigators studied a model of hemorrhage control in normal volunteers (9 men) by artery compression. The investigators noted that exsanguination from a femoral artery wound can occur in seconds and that it may be seen more often now with more body armor use. The investigators wrote that military physicians recommend compression of the common iliac arteries with a knee or a fist as a temporary measure. The supine volunteers (on the floor) had a dumbbell from a gymnasium placed vertically on a common bath towel (tightly bundled to roughly the size and shape of an adult knee) near the umbilicus in order to see if the artery blood flow was stopped. Using ultrasound, the investigators measured the flow with various weights. Flow was consistently stopped given that the weight was adequate and the compression was accurate. Aortic compression of 80 to 140 pounds led to no flow in the common femoral artery. For all 9 volunteers, up to 80 pounds of pressure over the distal iliac artery failed to decrease common femoral artery flow velocity, and no subject was able to tolerate more weight at that location. Therefore, there are adequate physiologic grounds on which to design a system for

hemorrhage control based on pressure point compression in this area, and the proximal portion of the common iliac arteries appears to be the target zone. The investigators concluded that flow to the common femoral artery can be stopped completely with pressure over the common iliac artery and that such pressure could be feasibly used in catastrophic wounds. Compression over the common iliac artery worked best, but a first responder still may need to apply upward of 120 pounds of pressure to stop arterial exsanguination.⁶⁴ Furthermore, as the study noted no complications, compression may be used safely.

A preliminary animal study, also from the Medical College of Georgia, examined the efficacy and safety of a novel, externally applied pneumatic abdominal tourniquet to halt blood flow from the abdominal aorta in 2 pigs.⁶⁵ This study demonstrated the device's efficacy. Although there was no sign of direct tissue injury, the rise in serum potassium in one animal was concerning, and further research was recommended.⁶⁵

Therefore, the physiological evidence indicates that a well-designed device could plausibly control hemorrhage. A consideration of how a device would be used follows.

CONCEPT OF OPERATIONS: DEVICE TRAITS FROM THE USER'S VIEWPOINT

The concept of how a junctional tourniquet would be used in war is yet to be fully developed in order to communicate the system characteristics to stakeholders, but regular tourniquets are a model from which adaptations can be used. For example, to save lives, a truncal tourniquet is designed to control prehospital bleeding, as is the goal of regular tourniquets. Regular tourniquets are an integrated capability for far-forward medical care to reduce mortality and morbidity associated with major battlefield wounds and injuries. We aim for truncal tourniquets to also be such a capability. Specifically, novel prototype tourniquets for hemorrhage control of truncal injuries on the battlefield may increase, like regular tourniquets, the duration of survival of a casualty so as to permit transport to a forward surgical facility. Longer survival is a practical objective, which permits better resuscitation and life-saving interventions. The intended use scenario is for a senior medic or a physician assistant working under the supervision of a physician at a forward location, such

as a battalion aid station. The intended users need adequate anatomic knowledge and specific device training to apply the device and control hemorrhage in the prehospital or far forward setting. The truncal tourniquet would permit hemorrhage control for casualty evacuation by occluding deep truncal vessels with distal bleeding by compressing sites where standard tourniquets cannot be applied. Desirable traits of candidate devices, presented in the Table, should fit within the needs of the user, in this case, senior medics in the field. Furthermore, the design of the candidate devices, the instructions on use, and the anatomic knowledge required constrain the device candidates to use by senior medics who are well trained in the specific device. The prehospital strategy was successful for regular tourniquets, first in special operations forces and then in conventional forces, and a similar tactic for truncal tourniquets is planned. The evidence of best tourniquet practice helped refine regular tourniquet doctrine serially, and a similar tactic is planned for truncal tourniquets. Current stakeholders include the device makers and users, the regulators (the US Food and Drug Administration), the researchers (Wake Forest University Medical Center, the United States Army Institute of Surgical Research), and the developers (United States Army Medical Materiel Development Agency). Interactions among participants have included a teleconference and correspondence which facilitated the regulatory pathway and approval of the Combat Ready Clamp as the first hemorrhage control device for prehospital use for groin hemorrhage. Orders for the Combat Ready Clamp have been placed for limited introduction into the field. Initial distribution in November 2010 was planned for a select unit, and if results are promising,

Desirable traits of candidate device.
Stops bleeding effectively from junctional areas such as the groin, pelvis, buttock, shoulder or neck
Compresses sites where regular tourniquets cannot fit
Safe to use
Can be used well in prehospital on the battlefield in tactical situations
Small
Lightweight
Low-cost
Easy to use; requires minimal training or familiarization
Quickly applied
Does not slip on tightening or in use
Provides easy release of compression
Easy to reapply
Long shelf life

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wider distribution will follow. The clamp is not yet evidenced in clinical practice, but some preliminary preclinical evidence, such as in cadavers, is promising.

Given this concept of how users would operate the device, delimitation of research models, knowledge gaps, and device development challenges can help guide the way forward.

ANIMAL AND HUMAN MODELS, RESEARCH GAPS, AND DEVELOPMENT CHALLENGES

In lethal animal models of exsanguination, groin or junctional areas are often selected and numerous hemostatic substances or dressings have shown variable capacity to control bleeding, while some improve survival.^{40,66-69}

Currently, there is a gap regarding the way in which junctional bleeding can be practically modeled and devices tested for efficacy in humans. For example, there are no well-established models to control bleeding in humans, and surrogate models such as normal volunteers have limitations. Current gaps in the literature include an establishment of a reliable human model of junctional hemorrhage that can be used to test several devices, as repeated testing in volunteers is uncomfortable. A recent Medical College of Georgia study using normal volunteers indicated that such compression by a weight (dumbbell) worked well, but testing was painful in one area, and numbers of tests were limited.⁶⁴ The scalability of the pressure exerted and the flow stopped gave further evidence of cause and effect between such compression and flow control, but ultrasonically detected flow in a normal artery was only a surrogate of bleeding. Perhaps a human cadaver model with simulated blood pumped out of a wound would permit proximal pressure point control of hemorrhage. Testing of device effectiveness rates with specific repeatable bleeding wounds may then be possible.

Human and animal data regarding the effects of compression on blood flow, hemorrhage, or swelling have some relevance to hemorrhage control solutions, but the works have had limited application to the real world. The compression of limbs decreases tissue perfusion which is most important in skeletal muscle, the limb tissue most sensitive to prolonged ischemia. The perfusion quality depends in part on the amplitude of the artery-venous pressure gradient.⁷⁰ The hydrodynamics of arterial hemorrhage indicate that the rate of

leakage (simulated hemorrhage) is associated both with the transmural pressure gradient and the area of the vessel opening (simulated laceration of the wall).³⁶ The lesion size of the vessel opening of simulated trauma resulting in hemorrhage has been associated with both the amplitude of the resultant drop of blood pressure and the magnitude of the counterpressure required for control.³² For short segments of vessels like arteries, increasing external pressure has little to no effect on flow within the vessel.³⁴ However, when long segments are compressed, the flow stoppage can occur at low or even subsystolic pressures.⁷¹ Evidence indicates that circumferential pneumatic compression of limbs at 20 to 30 mm Hg may control arterial bleeding and yet not interrupt limb perfusion.⁷² Although counterpressure at an arterial bleeding lesion can improve survival in animals, such benefits come at a physiologic cost, namely metabolic acidosis, particularly with prolonged duration.³⁵ Other gaps include doctrine of device use, adequate lesson plans, user training in specific devices, and casualty simulator use in assessing trainee competency.

CONCLUSION

If a candidate junctional hemorrhage control device can be designed from a mechanical standpoint to specifically compress the target tissues reliably and precisely, and be demonstrated as safe when tested in a volunteer study, then it could be a successful device for medics trained in its use. Fielding of such a device may prevent casualty deaths. Although the technology of a truncal tourniquet may have been available as long ago as 1831, the integrated systems approach that demonstrated the remarkable success of regular tourniquets recently was not. We discussed the gaps today in battlefield hemorrhage control, and we surmise that an integrated systems approach to junctional hemorrhage control is our current best hope in minimizing a current, common cause of preventable death on the battlefield.

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New Tourniquet Device Concepts for Battlefield Hemorrhage Control

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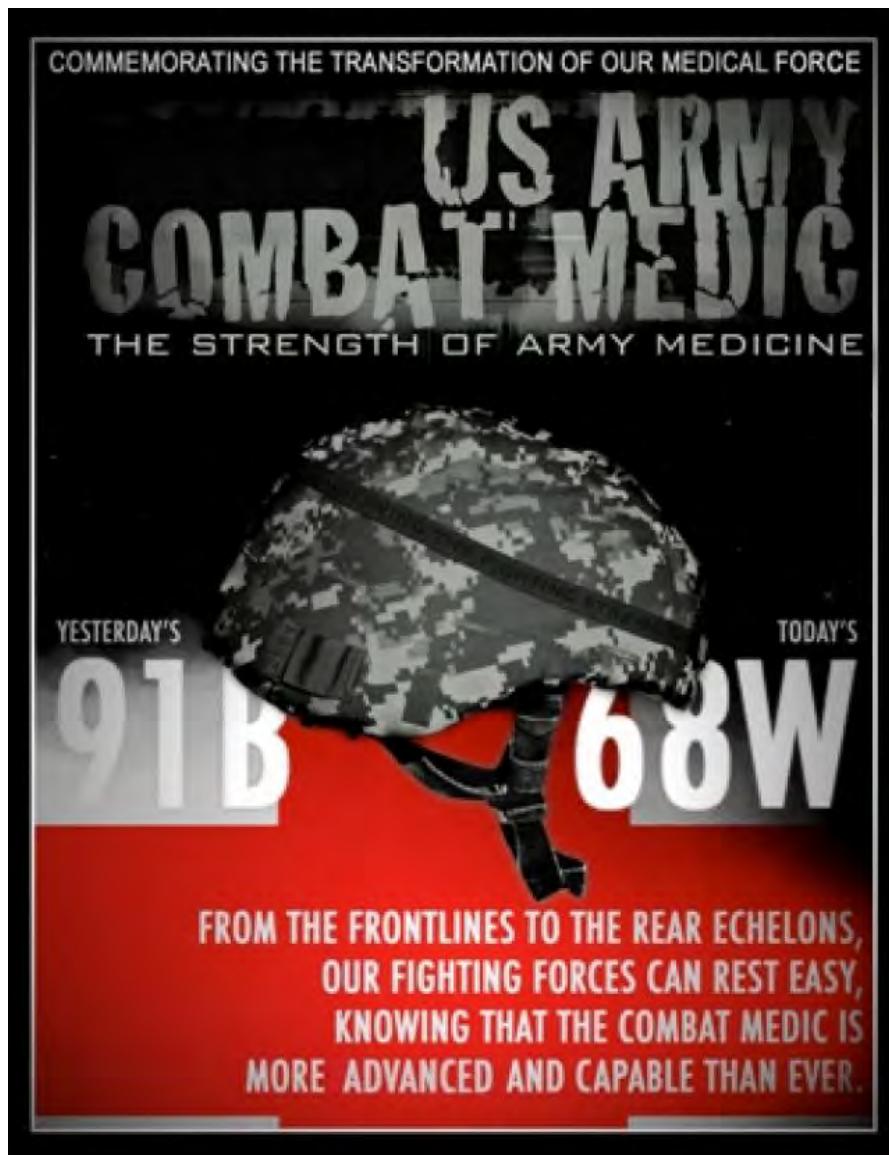
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The winning poster in the Combat Medic Transition poster contest, submitted by Sgt Christopher Giddinge, US Army Medical Research Institute of Infectious Disease, Fort Detrick, Maryland.

The Role of Normoventilation in Improving Traumatic Brain Injury Outcomes

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INTRODUCTION

Traumatic brain injury (TBI) is a leading cause of death and disability on the modern battlefield. During World War I, TBI was referred to as “shell shock.” Whether this entity was physical or psychological in origin was a subject of considerable debate. At the onset of World War II, British authorities banned use of the term in order to avoid contamination of the ranks by what was, by then, viewed as a factitious disorder. Resumed appreciation for the organic etiology of many of these injuries led to a new term during World War II, “postconcussion syndrome.”¹ Our current definition of TBI emphasizes that it is a “traumatically induced structural injury and/or physiological disruption of brain function as a result of an external force” with at least one of the following clinical signs^{2,3}:

- Decreased level of consciousness
- Amnesia for events surrounding injury
- Changed mental state at time of injury (confusion, disorientation, slowed thinking)
- Neurological deficits (weakness, loss of balance, change in vision, praxis, paresis/plegia, sensory loss, aphasia, etc.)
- Intracranial lesion

TBI is classified as mild, moderate, or severe^{2,3}:

- Mild—Glasgow Coma Scale* (GCS) 13-15; loss of consciousness (LOC) less than 1 hour; amnesia less than 24 hours.
- Moderate—GCS 9-12; LOC 1 to 24 hours; amnesia 1 to 7 days
- Severe—GCS 3-8; LOC more than 24 hours; amnesia longer than 7 days

Furthermore, the confusion experienced during World Wars I and II concerning whether TBI was psychological or physiological in origin has been resolved, at least in part, by recognizing that the symptoms of posttraumatic stress disorder and TBI overlap significantly, especially in the areas of attention, depression, and anxiety.^{3,4}

What is the importance of TBI on today’s battlefield? During the current conflicts in Iraq and Afghanistan (Operations Iraqi Freedom (OIF) and Enduring Freedom (OEF)), TBI has been a major cause of injury, leading some to call TBI the “signature injury” of these wars. Roughly half of these TBI cases are moderate or severe.⁵ Hospitalizations for TBI were greater in OIF than in OEF, and the overall trend was for an increase in TBI admissions in both theaters during the period 2003 through 2007.⁶ There are several possible explanations for an increase in survivors of TBI during OIF and OEF, compared to previous conflicts. Increased use of improvised explosive devices has subjected more casualties to the concussive effects of blast injury. One review indicated that 59% of blast injury patients admitted to the Walter Reed Army Medical Center had TBI.⁵ Improvements in body armor have decreased the number of lethal torso injuries, while improvements in helmets may have decreased the lethality of head injuries. Improvements in prehospital care, such as better tourniquets, and in hospital care, such as damage control surgery, have improved the survival of patients who otherwise would have died from nonhead trauma. Finally, improved screening has likely detected more cases of mild TBI.^{2,5,7}

Thus, a workshop cosponsored by the National Academy of Engineering and the Institute of Medicine reported that between January 2003 and April 2006,

*The Glasgow Coma Scale is a quick, practical, standardized system for assessing the degree of consciousness in the critically ill and for predicting the duration and ultimate outcome of coma, primarily in patients with head injuries. The system involves eye opening, verbal response, and motor response, all of which are evaluated independently according to a rank order that indicates the level of consciousness and degree of dysfunction. Source: *Mosby's Medical Dictionary*. 8th ed. St Louis, MO: Mosby-Year Book, Inc; 2009.

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28% of combat casualties from OIF and OEF receiving care at Walter Reed had a TBI.³ In a prospective study, nearly 15% of 2,525 infantry Soldiers from 2 combat brigades returning from Iraq in 2006 had an injury resulting in altered mental status or loss of consciousness.⁸ Kelly and colleagues⁹ reported on 982 US military deaths from OIF and OEF during the period 2003 through 2006. Considering the cause of death for those casualties deemed by the authors to have potentially survivable injuries, TBI constituted 9%.⁹ A study by Owens et al¹⁰ of wounding patterns in the same conflicts demonstrated a greater proportion of head and neck wounds compared to other body areas than in the previous 3 wars (Vietnam, Korea, and World War II). Specifically, head and neck wounds now constitute 30% of injuries. The overwhelming majority of these head and neck injuries are caused by explosions.¹⁰ Galarneau et al¹¹ queried data from the Navy-Marine Corps Combat Trauma Registry for OIF for a 7-month period during 2004. The data revealed that 115 patients had TBIs, of whom 13% died (killed in action or died of wounds). Another 43% were medically evacuated.¹¹

PREHOSPITAL CARE OF TBI CASUALTIES

What is the current prehospital standard of care for head-injured patients? In contrast to the high incidence of TBI on the battlefield, therapeutic options for prehospital combat casualty care of TBI patients remain limited. The Brain Trauma Foundation*, under a grant from the Defense and Veterans Brain Injury Center†, published *Guidelines for Field Management of Combat-Related Head Trauma* in 2005.¹² It includes the following recommendations:

- Airway: Patients with Glasgow Coma Scale score below 9 should be intubated, depending on operator skill.
- Oxygenation: Hypoxemia should be prevented, pulse oximetry should be performed, and oxygen saturation (SaO₂) maintained above 90%.
- Ventilation: Use of hyperventilation should be minimized, and limited to those patients exhibiting evidence of herniation. End-tidal CO₂ (ETCO₂) monitoring should be performed to help guide ventilation in intubated patients, with a goal of 25–35 mm Hg.

- Circulation: Hypotension should be avoided, the blood pressure measured, and fluid resuscitation administered for all casualties with systolic blood pressure below 90 mm Hg. Hypertonic saline may be preferable to isotonic saline as a resuscitation fluid.

The common theme in these prehospital guidelines is avoidance of further injury to the TBI patient. Avoidance of hypotension and hypoxia serve the goals of maintaining oxygen delivery to ischemic, or potentially ischemic, brain tissue. Avoidance of hyperventilation serves a similar goal, via the effect of the PaCO₂ (partial pressure of carbon dioxide in arterial blood) on cerebral blood flow. It is well known that a primary determinant of cerebral blood flow is the PaCO₂. A decrease in the PaCO₂ causes cerebral vasoconstriction and a decrease in cerebral blood flow. Thus, the only indication for hyperventilation in the brain-injured patient is impending herniation. In this situation, hyperventilation and decreased cerebral blood flow may decrease intracranial pressure enough to forestall death, buying time for other measures such as diuresis, hypertonic fluid infusion, and/or decompressive craniectomy to be performed. Short of this, hyperventilation and hypocapnia cause decreased blood flow to ischemic brain tissue, worsening outcomes following TBI. Because of these concerns, some authors recommend against performing hyperventilation in TBI patients without monitoring the jugular venous oxygen saturation, partial pressure of oxygen in brain tissue, or cerebral blood flow.¹³

CLINICAL DATA ON PREHOSPITAL VENTILATION OF TBI PATIENTS

How successful are we at achieving these goals for ventilation during prehospital care? CPT John Ritchie and colleagues from the US Army Institute of Surgical Research conducted a prospective observational study of TBI patients admitted to a single combat support hospital (CSH) in Iraq during the period 2007 through 2009. These patients were all intubated, either in the prehospital setting or upon arrival at the CSH emergency department. The partial pressure of carbon dioxide (PCO₂) was measured either in arterial blood (PaCO₂), or in venous blood (PvCO₂) with estimation of the PaCO₂. A PaCO₂ of 35–40 mm Hg was assumed to be the appropriate therapeutic target range. None of the patients who were ventilated by bag-valve mask before arrival at the CSH had a PaCO₂ in the target range, and only 41% of patients who were intubated (and then bag ventilated) before arrival were in the

*Information available at: <http://www.braintrauma.org/>

†Information available at <http://www.dvbc.org/>

target range. (No patients in this study were intubated and then ventilated by mechanical ventilator.) CPT Ritchie (oral communications, 2010) and his colleagues concluded that improvements in technology may be needed to improve this aspect of care.

What is the impact of errors in ventilation and oxygenation on mortality? Davis and colleagues in San Diego have studied the problem of prehospital ventilation of head-injured civilian trauma patients for many years. Using data from San Diego County, they demonstrated that, contrary to common belief, paramedic-performed rapid sequence intubation was associated with an increase in mortality and a decrease in good outcomes compared with historical controls.¹⁴ In a subsequent analysis, both hyperventilation and severe hypoxia were shown to be independently associated with increased mortality.¹⁵ A trauma registry study of over 13,000 patients confirmed that prehospital intubation was associated with increased mortality in patients with moderate to severe head injury.¹⁶ Davis et al then expanded their analysis of the San Diego data, finding that both hyperventilation and hypoventilation were associated with worse outcomes in intubated, but not in nonintubated, head-injured patients. Furthermore, they found an optimal range for prehospital PaCO₂ of 30-49 mm Hg.¹⁷ A recent publication by the same group using Trauma Injury Severity Score methodology refined these conclusions by documenting that intubation improved survival in a subset of severely injured patients with low predicted survival.¹⁸ Other authors report findings similar to those by Davis et al. Chi and colleagues¹⁹ prospectively enrolled patients with head injuries into an observational multicenter study. Of 150 patients, 57 had prehospital "secondary insults" of hypotension or hypoxia. Hypoxia increased mortality and the Disability Rating Scale. The combination of hypoxia and hypotension had an additive effect on these measures.¹⁹

END-TIDAL CARBON DIOXIDE MONITORING

What can be done to improve prehospital ventilation in head-injured patients? The most obvious solution is to provide medics with an estimate of the PaCO₂. The most immediately available measurement for this estimate is the ETCO₂, available on many transport monitors in the field today (eg, Propaq MD Monitor, ZOLL Medical Corporation, Chelmsford, MA). The major problem with using the ETCO₂ as an estimate of the PaCO₂ is the fact that the difference (gradient)

between the 2 numbers varies, depending on various cardiopulmonary factors. The most important of these factors is the *physiological dead space*. The physiological dead space (V_D) is composed of the *anatomic dead space* and the *alveolar dead space*. Anatomic dead space is the volume of the conducting air spaces, ie, the trachea, bronchi, bronchioles, and other portions of the airway which conduct air but which do not participate in gas exchange. Alveolar dead space is the volume of unperfused spaces at the alveolar level.^{20,21} Wagner pointed out that in addition to unperfused alveoli, high ventilation-perfusion compartments (or, less frequently, low ventilation-perfusion compartments) also contribute to an increased alveolar dead space.²² Clinical conditions which increase the PaCO₂-ETCO₂ gradient include decreased pulmonary perfusion (eg, hemorrhagic shock causing decreased cardiac output, pulmonary embolism, cardiac arrest, air embolism), and airway obstruction (including severe bronchospasm).^{21,23} Acute lung injury and acute respiratory distress syndrome increase V_D and thus the PaCO₂-ETCO₂ gradient, likely by means of pulmonary vasoconstriction, microthrombi, and/or endothelial swelling.²⁴

Considering the fact that multiple factors present in trauma patients may influence the PaCO₂-ETCO₂ gradient, it is evident that the ETCO₂ is not a perfect surrogate for the PaCO₂. Several of the best studies of this problem have been conducted in Europe, where physicians frequently provide prehospital care, and arterial blood gas analysis is therefore feasible in that environment. Belpomme et al²⁵ prospectively measured PaCO₂ and ETCO₂ during transport of 100 prehospital, mechanically ventilated patients with various diseases. The main finding was that the PaCO₂-ETCO₂ gradient varied widely among patients, but did not differ significantly during transport (mean values of 8.6 ± 13.5 mm Hg at start, and 7.3 ± 13.0 mm Hg at end transport).²⁵ Helm and colleagues²⁶ conducted a prospective study of 97 mechanically ventilated trauma patients. Patients for whom the attending anesthetist could see the ETCO₂ monitor had a higher incidence of normocapnia than those in situations where the anesthetist was blinded. Interestingly, patients with severe TBI or chest trauma, hemodynamic instability, or high injury severity scores were more likely to be ventilated appropriately. In that study, the ETCO₂ target was 30-35 mm Hg for regular patients, and 25-30 mm Hg for hemodynamically unstable or chest trauma patients.²⁶

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Yamanaka and Sue,²⁷ among others, have demonstrated that directly measured V_D correlates with the PaCO_2 - ETCO_2 gradient. The usual method of measuring V_D , however, requires collection of expired gas in a Douglas bag and is thus clinically impractical.²⁷ One way to overcome the limitations of conventional capnography for estimation of the PaCO_2 is *volumetric* capnography. Conventional devices measure the ETCO_2 by analyzing the partial pressure of CO_2 in exhaled air as a function of time. But the volumetric capnograph (volume-based capnograph) provides additional information on pulmonary function by analyzing the partial pressure of CO_2 in exhaled air as a function of exhaled volume. This approach provides data which are independent of the expiratory flow rate.²⁸ The volumetric capnograph consists of 3 phases. Phase I is a flat, low CO_2 phase and corresponds to exhalation from the anatomic dead space. Phase II is a steeply rising phase and corresponds to the exhalation of mixed air. Phase III is a plateau phase with a slowly rising slope which corresponds to exhalation of alveolar air. The different portions of this curve can be quantified (parameterized). It is then possible to estimate V_D using a method called the “single-breath test for carbon dioxide.”²⁹ This method requires simultaneous measurement of the PaCO_2 , and use of the Enghoff modification of the Bohr equation

$$\frac{V_D}{V_T} = \frac{\text{PaCO}_2 - \text{PECO}_2}{\text{PaCO}_2}$$

where PECO_2 is the mixed exhaled PCO_2 measured by the volumetric capnograph, and physiological dead space is expressed as a fraction of the total tidal volume (V_T).³⁰ The following data from McSwain et al demonstrate the relationship between V_D/V_T measured by volumetric capnography, and the PaCO_2 - ETCO_2 gradient³⁰:

V_D/V_T Range	<0.40	0.41-0.55	0.56-0.70	>0.70
PaCO_2 - ETCO_2 gradient	0.3 ± 2.1	5.9 ± 4.3	13.6 ± 5.2	17.8 ± 6.7
Correlation coefficient (PaCO_2 vs ETCO_2)	0.95	0.88	0.86	0.78

It can be seen that V_D/V_T is a function of the PaCO_2 - ETCO_2 gradient (higher V_D/V_T is associated with higher gradient), and that within each V_D/V_T range, the correlation between PaCO_2 and ETCO_2 is reasonably high. In other words, if V_D/V_T is known and stable, ETCO_2 becomes a reasonable surrogate for PaCO_2 .

The problem is that calculation of V_D/V_T requires measurement of the PaCO_2 , and thus still remains “out of bounds” for prehospital combat casualty care. Nevertheless, it would be premature to discard volumetric capnography. The capnograph likely contains information which can be harnessed to refine our ability to predict PaCO_2 . An analogous concept was described by Patel and colleagues in the diagnosis of pulmonary embolus.³¹ These authors trained an artificial neural network (ANN) using 17 variables from the volumetric capnograph to estimate the presence or absence of pulmonary embolus (PE). In 53 test subjects, PE was detected with a sensitivity of 100% and a specificity of 48%.³¹ Rayburn also described an ANN which uses the volumetric capnograph to estimate the PaCO_2 .³² This ANN was trained using 82 datasets from patients with a variety of pulmonary conditions. According to Rayburn (oral communication, D. B. Rayburn, 2009), the correlation coefficient between estimated and measured PaCO_2 using this ANN was high, and the difference between the 2 values was no greater than ± 2 mm Hg. We are currently validating this ANN using data from a porcine model of acute respiratory diseases secondary to pulmonary contusion.

TRANSCUTANEOUS CO_2

Are more accurate methods of estimating PaCO_2 available? The closest and most promising solution is the direct measurement of CO_2 at the level of the tissue in the form of transcutaneous CO_2 ($\text{P}_{\text{TC}}\text{CO}_2$). In a recent study, Hinkelbein and colleagues prospectively measured PaCO_2 , ETCO_2 , and $\text{P}_{\text{TC}}\text{CO}_2$ in 34 patients scheduled for interhospital transport.³³ This study was unique in that these 3 measurements were compared simultaneously. $\text{P}_{\text{TC}}\text{CO}_2$ more accurately estimated PaCO_2 when compared to ETCO_2 . Not surprisingly, subgroups with high FiO_2 (fraction of inspired oxygen) or with respiratory failure had significant increases in the PaCO_2 - ETCO_2 gradient, highlighting the limitations of ETCO_2 measurement.³³ The reliability of $\text{P}_{\text{TC}}\text{CO}_2$ has been described previously in other populations.^{34,35} Although very promising and available from multiple vendors (SenTec Digital Monitoring System, Therwil, Switzerland; TOSCA, Linde, Basel, Switzerland; Tina TCM4 device, Radiometer Copenhagen, Bronshoj, Denmark), $\text{P}_{\text{TC}}\text{CO}_2$ has a number of limitations which would make it difficult to field without some refinement. The greatest limitation is the relative bulk of the monitors,

which are only available as standalone devices. Frequent calibrations using a CO_2 standard, incorporated within each device, are required. Additionally, these devices employ heat-generating sensors, which creates a potential for thermal injury. Like many noninvasive sensors, signal quality is significantly diminished in shock states such as hemorrhage.

CONCLUSION

Traumatic brain injury, including moderate and severe TBI, is a significant and growing problem on the contemporary battlefield. In civilian studies, ventilation which achieves a PaCO_2 within a target range is associated with improved survival following TBI. However, data from the battlefield indicate that such “normoventilation” is achieved in a minority of casualties who require ventilatory support. In order to address this problem, both training and technological improvements are needed. Medics should receive training directed at improving their skills in hand ventilation and, in particular, should be trained in the importance of avoiding over-ventilation in patients with TBI. Medics should also be provided with technology which increases their ability to ventilate their casualties in a manner which achieves the target PaCO_2 . We see 3 options for doing this:

Measurement of the ETCO_2 using traditional, time-based capnography, with use of rules for adjusting the rate and depth of ventilation in order to achieve a desired target range for the ETCO_2 . This was the method successfully performed by Helm et al.²⁶ This approach has the disadvantage of adding an additional sensor to a future prehospital vital signs monitor, but small, lightweight ETCO_2 monitors are now available. Helm’s target ranges for the ETCO_2 appear reasonable (30-35 mm Hg for stable patients, and 25-30 mm Hg for unstable patients), but the impact of dead-space ventilation cannot be completely overcome.

Estimation of the PaCO_2 using volumetric capnography and an ANN or similar machine-learning approach.³² In addition to the points made above about time-based capnography, this method would require further validation prior to implementation.

Estimation of the PaCO_2 using another technique such as P_{TCO_2} , as described by Hinkelbein and others.³³ This method would require use of an additional sensor

which is not commonly used in prehospital or critical care settings at present, and would also require sensor improvements. Also, the performance of such a sensor in patients with hemorrhagic shock would have to be validated. On the other hand, P_{TCO_2} has the potential advantage of providing an estimate of PaCO_2 which is independent of dead-space ventilation.

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Advances in Prehospital Burn Resuscitation for the Combat Injured

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INTRODUCTION

Wartime often leads to advances in medical care as unique problems that surface in an austere environment necessitate urgent solutions. Current combat operations in Iraq and Afghanistan have been no different in their impact on burn care, specifically with regard to fluid resuscitation. The influx of severely burned combat casualties globally evacuated to our burn center at the US Army Institute of Surgical Research in Fort Sam Houston, Texas [hereinafter referred to as the Burn Center], began in early 2003 and has continued through 2010. As the flow of those casualties continued, we discovered processes in need of improvement and addressed them in a timely and robust manner. Such initiatives included reevaluation of the initial fluid resuscitation of burn casualties, as well as continued resuscitation during en route care.

A SIMPLIFIED APPROACH TO FLUID RESUSCITATION IN BURNS

Overview

Arguably one of the more challenging aspects of the initial management of severe burn casualties is the fluid resuscitation necessary to prevent or mitigate burn shock and multiple organ failure. Longstanding recommendations provided by the American Burn Association (ABA) include initiating fluid resuscitation of the burn patient utilizing lactated Ringers solution, at an infusion rate of 2 to 4 cc/kg/percentage total body surface area (TBSA) burn administered over the first 24 hours following the burn injury (postburn); providing one-half of estimated fluid over the first 8 hours, and the remainder over the next 16 hours.¹ This ABA resuscitation guideline is intended to give the provider a prediction of how much fluid should be given over an entire 24-hour period. Although, predicting the total amount of volume that the patient *should* receive in a 24-hour period via formula is helpful in assessing the precision of the

resuscitation post hoc, it should not be used to strictly dictate what the patient receives hour to hour. Once initiated, the ultimate goal of fluid resuscitation is to maintain end-organ perfusion by gradually restoring fluid balance while simultaneously replacing insensible losses and avoiding the consequences of both under- and over-resuscitation. Optimal care of the burn casualty during the early phase of resuscitation requires an attentive medic titrating fluid therapy based on a compilation of various endpoints centered on a goal of maintaining a urine output of 30-50 ml/hr. Urine output of between 30-50 ml/hr is generally accepted as a corollary of renal perfusion indicative of adequate initial resuscitation in casualties with isolated burn injuries. Thus, the practical purpose of any formula is to identify an appropriate starting point for the resuscitation, the initial infusion rate. A prediction of how the first 24 hours *should* go, the centerpiece of the current resuscitation guidelines, may place the focus of the resuscitation away from the “art” of resuscitation.

Prehospital Burn Resuscitation

Despite general instructions that the predicted fluid requirements are designed to serve only as guidelines, and that actual resuscitation should be based on patient response, many nonburn providers either err on the side of adhering strictly to the formulae regardless of patient response, or not utilizing them at all. A post hoc analysis of prehospital fluid resuscitation practices was performed using data collected from an institutional review board-approved prospective observational trial assessing resuscitation practices in the Burn Center. We reviewed the records of 39 civilian burn patients admitted to the Burn Center with severe thermal injury greater than 20% TBSA. At the time of admission to the Burn Center, we carefully recorded the time of burn, total prehospital fluids given, weight in kilograms, and estimated percentage TBSA burn. We used this data to estimate initial rate

of fluid begun for each patient in the first hour postburn. We then determined the formula, in cc/kg/percentage TBSA, that would have been used to derive that initial rate. Essentially, we wanted to evaluate which, if any, formula the pre-Burn Center providers were using, in cc/kg/percentage TBSA, to calculate the patient's initial fluid resuscitation rate. The results (Table 1) were plotted (Figure 1) and compared to current ABA guidelines. We discovered that only 21% of all patients (8/39) were being initiated on a fluid rate what would have been derived using the 2-4 cc/kg/percentage TBSA formula recommended by the ABA. Thus, we concluded that prehospital providers situated in a large city in the United States were not using a formula to determine the initial fluid rate. If US prehospital providers are not using a formula, it is highly unlikely that providers deployed to austere environments, often tending to multiple casualties simultaneously, are using a formula.

The most likely reason for this lack of adherence among prehospital providers is the fact that the formulae are too complex, requiring multiple steps.

Table 1. The calculated initial fluid resuscitation rates for 39 patients. Values are plotted in Figure 1.

cc/kg/ percentage TBSA	Subject number	cc/kg/ percentage TBSA	Subject number
0.00	CL-30	5.19	CL-16
1.05	CL-38	5.59	CL-06
1.18	CL-40	5.70	CL-09
1.24	CL-05	5.79	CL-11
1.43	CL-19	5.89	CL-14
1.73	CL-24	6.35	CL-39
2.30	CL-21	6.41	CL-20
2.58	CL-02	6.85	CL-10
2.59	CL-15	7.51	CL-23
2.60	CL-27	7.67	CL-12
2.71	CL-33	7.77	CL-34
2.77	CL-35	8.30	CL-28
3.27	CL-29	8.64	CL-36
3.91	CL-18	8.90	CL-31
4.17	CL-08	8.94	CL-07
4.44	CL-26	11.82	CL-17
4.57	CL-25	12.23	CL-01
4.76	CL-04	12.59	CL-03
4.88	CL-22	20.13	CL-37
5.02	CL-13		

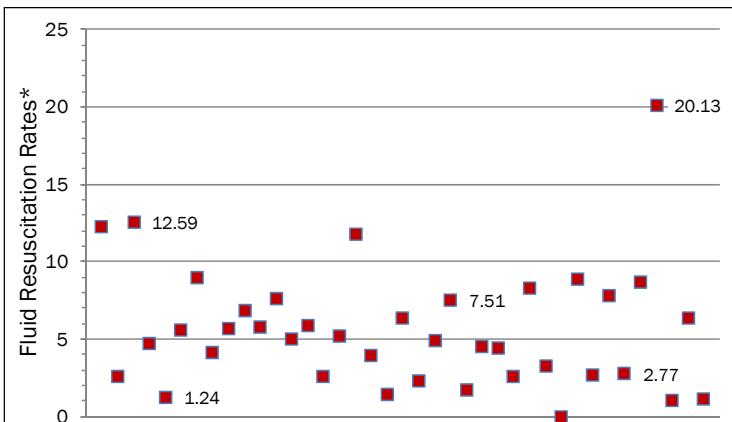


Figure 1. Post hoc analysis of prehospital fluids administered to burn patients. Individual values for each of 39 patients shown in Table 1 are plotted to illustrate distribution of necessary fluid resuscitation rates across the sample population. Certain numerical values are shown to provide perspective.

*In cc/kg/percentage TBSA burned.

For example, the calculated rate for a patient weighing 70 kg who has suffered a 50% TBSA burn requires 4 separate variables (time, weight, surface area, and volume) with a minimum of 4 computations that must be performed. Such calculation results in an initial fluid rate of 437 ml/hr when using the Modified Brooke formula (2 cc/kg/percentage TBSA).¹ The likelihood of a combat provider at the level I or level II echelon of care performing this calculation under duress or in the face of multiple casualties is exceedingly low.

The Rule of 10

Surely, a more simple method could be found to derive this initial fluid rate. Enter the "Rule of 10" (see inset below). Recently conceived and validated in silico [computer simulation] at the US Army Institute of Surgical Research (ISR),² the Rule of 10 is a simplified formula that calculates the initial fluid resuscitation rate by multiplying the estimated burn size by 10. In the example given above, multiplying the surface area of burn (50%) by 10 results in an

The US Army Institute of Surgical Research Rule of 10

Estimate burn size (using the Rule of Nines) to the nearest 10% TBSA.

Multiply that by 10 to calculate the Initial Fluid Rate for patients weighing 40 to 80 kg.

Increase fluid rate by 100 cc/hr for every 10 kg of body weight above 80 kg.

initial fluid rate of 500 ml/hr, a number falling within the acceptable range of 437 ml/hr (2 ml/kg/TBSA) and 875 ml/hr (4 ml/kg/TBSA) derived from the ABA consensus recommendation. Subsequent and serial adjustments in fluid infusion rate are then based upon response to resuscitation. As demonstrated by our *in silico* validation, this simplified equation provides an acceptable starting point for the vast majority of patients weighing more than 40 kg. To accommodate burn patients weighing over 80 kg, an increase of 100 ml/hr is added for each 10 kg over 80 kg.

The Rule of 10 allows the combat prehospital providers at levels I and II echelons of care to easily implement the fluid resuscitation, and then to shift the focus towards the patient's response to the resuscitation in order to dictate the amount of fluid administered over the first 24 hours. Traditional resuscitation formulas can still be used as benchmarks to assess the adequacy of the resuscitation. This formula has recently been adopted by the Committee on Tactical Combat Casualty Care*, and has been included in a new chapter for treatment of burn casualties in the military version of the prehospital trauma life support manual published by the National Association of Emergency Medical Technicians.³

EN ROUTE CARE

Identification of the problem

For US Warriors burned in the Iraq and Afghanistan theaters, the initial burn resuscitation—the first 24 to 48 hours postburn—is routinely performed by providers possessing variable levels of experience in burn care. In addition, multiple handoffs occur while the patient is being transported. It is common for 4 or more teams of providers to manage a military casualty with severe burns prior to the patient's arrival at the Burn Center for definitive care. Given that variations in practice exist among different sets of providers, variability in the way care is delivered during the resuscitation is unavoidable. In addition, the teams rotate out of theater every 4 to 6 months, which results in the loss of the knowledge and experience gained during their deployment. Together, these issues provide an underpinning that makes it difficult to standardize care in this environment. The multitude of challenges faced by deployed providers with regard to immediate burn care has previously been described.⁴

*A committee of the Defense Health Board, US Department of Defense.

Table 2. The Army Institute of Surgical Research burn resuscitation clinical practice guidelines.

At 12 to 18 hours postburn, calculate the PROJECTED 24-hour resuscitation if fluid rates are kept constant. If the projected 24-hour resuscitation requirement exceeds 6 cc/kg/percentage TBSA, the following steps are recommended:

Initiate 5% albumin early as described in the *Emergency War Surgery Handbook*.⁵

Check bladder pressures every 4 hours.

If urine output (UOP)<30 cc/hr, strongly consider the placement of a pulmonary artery (PA) catheter to guide resuscitation with specific pulmonary capillary wedge pressure (PCWP) and mixed venous saturation (SvO₂) goals (goal PCWP 10 to 12, SvO₂ 65% to 70%). If a PA catheter placement is not practical, consider monitoring the central venous pressure (CVP) from a subclavian or internal jugular vein along with central venous (ScvO₂) saturations (goal CVP 8 to 10, ScvO₂ 60% to 65%).

If CVP or PCWP is not at goal, increase the fluid rate.

If CVP or PCWP is at goal, consider vasopressin 0.04 unit/minute to augment the mean arterial pressure (and thus UOP) or dobutamine 5 mg/kg/min (titrate until SvO₂ or ScvO₂ at goal). The maximum dose of dobutamine is 20 mg/kg/min.

If both CVP or PCWP and SvO₂ or ScvO₂ are at GOAL, stop increasing fluids (even if UOP<30 cc/hr). The patient should be considered hemodynamically optimized, and the oliguria is likely a result of established renal insult. Some degree of renal failure should be tolerated and expected. Continued increases in fluid administration despite optimal hemodynamic parameters will only result in "resuscitation morbidity" that is oftentimes more detrimental than renal failure.

If the patient becomes hypotensive along with oliguria (UOP<30 cc/hr), then follow the hypotension guidelines.

Every attempt should be made to minimize fluid administration while maintaining organ perfusion. If UOP>50 cc/hr, decrease the fluid rate by 20%.

After 24 hours, lactated Ringer infusion should be titrated down to maintenance levels and albumin continued until the 48-hour mark.

Burn Guidelines

As a result of these challenges and in an effort to standardize care, in November 2005, we developed the burn resuscitation clinical practice guidelines (Table 2), as well as a burn resuscitation flow sheet (Figure 2). Serendipitously, the Joint Theater Trauma System had been established in early 2005, and it became the vehicle that allowed us to immediately disseminate the guidelines and burn care flow sheet. Within weeks of identifying the insufficiency of documentation and lack of standardization of en route care, a solution was developed and disseminated widely throughout the

Advances in Prehospital Burn Resuscitation for the Combat Injured

JTTS Burn Resuscitation Flow Sheet										Page 1
Date:	Initial Treatment Facility:			Estimated fluid vol. pat. should receive						
Name	SSN	Pre-burn Est. Wt (kg)	%TBSA	1st 8 hrs	2nd 16th hrs	Est. Total 24 hrs				
Date & Time of Injury				BAMC/ISR Burn Team DSN 312-429-2876						
Tx Site/ Team	HR from burn	Local Time	Crystallloid (ml)	Colloid	TOTAL	UOP	Base Deficit	BP	MAP (>55)/ CVP	Pressors (Vasopressin 0.04 u/min)
1st										
2nd										
3rd										
4th										
5th										
6th										
7th										
8th										
Total Fluids 1st 8 hrs:										
9th										
10th										
11th										
12th										
13th										
14th										
15th										
16th										
17th										
18th										
19th										
20th										
21st										
22nd										
23rd										
24th										
24 hr Total Fluids:										

Figure 2. The burn resuscitation flow sheet developed and distributed by the ISR in 2005. It is used to document the first 72 hours of care received by burn patients as they move through evacuation channels en route to the Burn Center.

combat theater. This accomplishment is an example of how the system enabled us to establish guidelines very quickly and educate providers across the evacuation chain. The flow sheet has been a valuable documentation tool to record the first 72 hours of resuscitation as patients move through the various echelons of care. At each level of evacuation, the flow sheet ensures the appropriate repeated assessment of the resuscitation, which is vital in all difficult resuscitations. The flow sheet also provides our staff with the data necessary to evaluate the patient's initial resuscitation course when patients arrive at the Burn Center.⁶ This resuscitation tool has been important in

providing continuity in documentation as well as system-wide standardization of care.

Follow-up Data

Improvement of outcomes as a result of this intervention has also been previously described by Ennis et al.⁷ A 50% decrease in the composite endpoint of abdominal compartment syndrome and mortality was revealed when the outcomes of those evacuated after the release of the guidelines were compared to those of casualties who were evacuated before the guidelines were in place. This finding by our group illustrates how our current military trauma

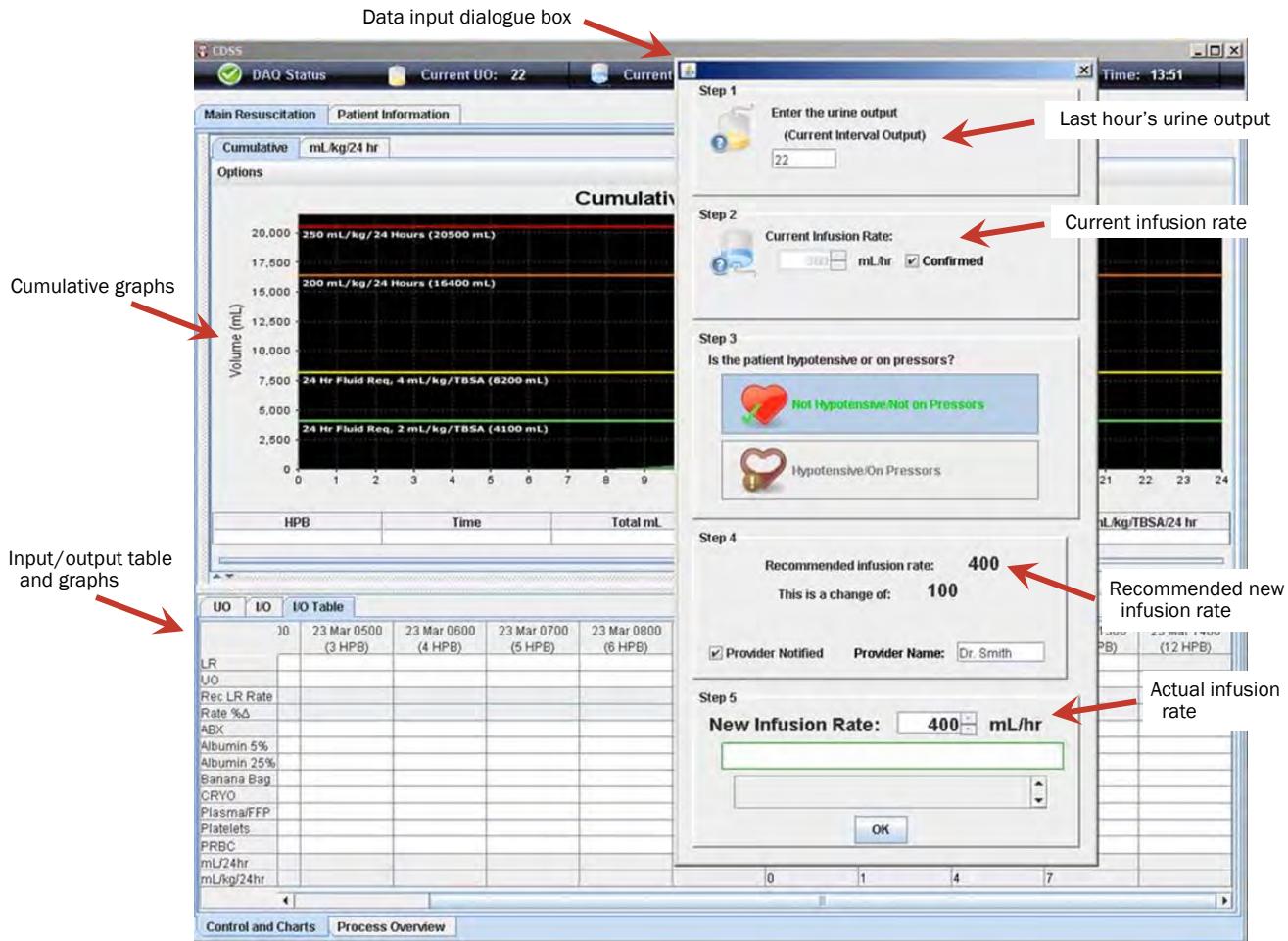


Figure 3. Reproduction of the input/output screen of the burn resuscitation decision support system developed by the Army Institute of Surgical Research.

landscape allows us to adapt as a system, identify problems, and alter the way care is delivered in an effort to improve outcomes.⁷

Decision Support

Nonetheless, the burn flow sheet, a valuable and necessary tool, is not perfect. It helps document what was done, but does not assist the provider in the determination of how a resuscitation should be performed. Much variability still exists with regard to how burn resuscitation is conducted from patient to patient. In order to provide better guidance to nonburn providers and to further standardize care, we have developed a computer-based decision support algorithm to assist the deployed care provider.⁸ As shown in Figure 3, urine output levels are automatically captured by the system hourly, which generates a recommendation for fluid rates based on the trend of

the last few hourly urine outputs. Application of this decision support system (DSS) in our intensive care unit at the Burn Center was evaluated. Compared to 40 control patients who were resuscitated without the DSS, resuscitation using the DSS in 26 consecutive patients resulted in significantly lower fluid requirements during the initial 48 hours following the burn injury (27 ± 14 vs 15 ± 6 liters, $P < .05$). Furthermore, compared to control patients, the DSS was able to maintain patients between the urine output targets of 30 to 50 ml/hr over a higher percentage of the time (22% vs 37%, $P < .05$).⁹

THE FUTURE

One of the ISR's primary objectives related to resuscitation is to facilitate the fielding of a user-friendly tool designed for prehospital and hospital-based providers who do not routinely care for burn

casualties. The tool may ultimately be delivered in the form of a handheld device (Figure 4) or be incorporated into an intravenous fluid pump. Regardless of the technology used, the key objective is to incorporate a functional and tested version of a burn resuscitation DSS to assist providers in the resuscitation of burn casualties based on real-time physiologic parameters; to be available during all phases of care or evacuation. Ultimately, it is hoped that these efforts will result in improved resuscitation practice, more efficient transmission of clinical data, less morbidity associated with resuscitation, and overall improved outcomes.

Other areas of interest include the choice of resuscitation fluid used in the forward environment. Special operations forces and other highly mobile combat teams are often limited in the amount of medical supplies immediately available to them. The use of colloids and plasma substitutes continues to spark much discussion among prehospital providers. Current research in this area may result in further ways to minimize complications associated with over- and under-resuscitation of the burn casualty, as well as other battlefield casualties.



Figure 4. Artist drawing of a conceptual hand-held device to provide access to the burn resuscitation decision support system.

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Advanced Technology Development for Remote Triage Applications in Bleeding Combat Casualties

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ABSTRACT

Combat developers within the Army have envisioned development of a “wear-and-forget” physiological status monitor (PSM) that will enhance far forward capabilities for assessment of Warrior readiness for battle, as well as for remote triage, diagnosis and decision-making once Soldiers are injured. This paper will review recent work testing remote triage system prototypes in both the laboratory and during field exercises. Current PSM prototypes measure the electrocardiogram and respiration, but we have shown that information derived from these measurements alone will not be suited for specific, accurate triage of combat injuries. Because of this, we have suggested that development of a capability to provide a metric of circulating blood volume status is required for remote triage. Recently, volume status has been successfully modeled using low-level physiological signals obtained from wearable devices as input to machine-learning algorithms; these algorithms are already able to discriminate between a state of physical activity (common in combat) and that of central hypovolemia, and thus show promise for use in wearable remote triage devices.

Accurate, early diagnosis of hemorrhage to enable timely application of life saving interventions is a high priority for the Army Medical Department, since hemorrhage remains a leading cause of death on the battlefield.^{1,2} Survival rates increase when victims requiring immediate intervention are correctly and expeditiously identified,³ but methods of assessing the severity of hemorrhage based on current triage algorithms are severely limited. Despite ongoing study, mental status and low blood pressure (systolic < 90 mm Hg) are still considered to be the best indicators of the need for life-saving interventions,⁴⁻⁶ even though the unreliability of arterial blood pressure as an indicator of blood loss was recognized as early as World War II.^{7,8} In trauma and combat casualty care medicine, a profound need exists for improved physiological algorithms that will provide a reliable early indication of hemodynamic instability, and provision of these algorithms has been the focus of our research efforts.⁹ Indeed, delays in identification and control of hemorrhage in the prehospital phase of treatment accounted for a large percentage of potentially preventable deaths during Operation Iraqi Freedom.² In recognition of this need,

the Combat Casualty Care Research Program of the US Army Medical Research and Materiel Command established a specific task area (Advanced Capabilities for Emergency Medical Monitoring) in 2002 to investigate new ways to meet capability gaps in medical monitoring, particularly in the prehospital phase.

Physiologic status assessment in casualties can be problematic in the military setting, where physical access to the injured individual may be complicated by terrain, weather and hostile action. Likewise, some civil sector settings may challenge first responders, particularly when victims are located remotely. The lack of a remote triage capability may therefore result in the medic attending to either *a*) a Soldier who is uninjured but caught in the vicinity of combat; or *b*) a Soldier under severe fire who has an injury that is deemed unsalvageable.¹⁰ Indeed, a combat medic may place himself in harm’s way to assist a Soldier who may not even be injured or may be unsalvageable. Data collected during the Vietnam War indicate that the fatality rate of US Army medics was double that seen in infantrymen.¹¹ Anecdotally, this risk continues in the current combat setting, as medics routinely place

themselves in potentially vulnerable positions in order to physically assess and treat a wounded Soldier. It is therefore desirable to provide a remote triage capability that protects combat medics while accurately assessing the injury severity of a wounded Soldier.

WEAR-AND-FORGET MONITORING SYSTEMS

The concept of continuous, remote, physiological monitoring has gained traction for use by War-fighters,^{12,13} astronauts,¹⁴ and emergency first responders,¹⁵ and implementation systems have been actively pursued by military developers.^{12,13} In particular, the US Army has embarked on a program to develop a “wear-and-forget” monitoring system that will wirelessly provide continuous streams of physiological data from individual Soldiers to a medic-held personal data assistant (Figure 1). It should be noted that the initial impetus for development of a remote triage system evolved from the desire for continuous monitoring capabilities to assess the physiological status of Soldiers to determine their readiness for battle, thereby providing a greater degree of operational and situational information to tactical commanders. Hence, as originally envisioned, these monitoring systems include the capability to measure hydration status, body core temperature, and the amount of sleep obtained.¹³ It was realized early, however, that physiological responses to combat injury might also be measured by these systems, and could provide the capability for remote triage.

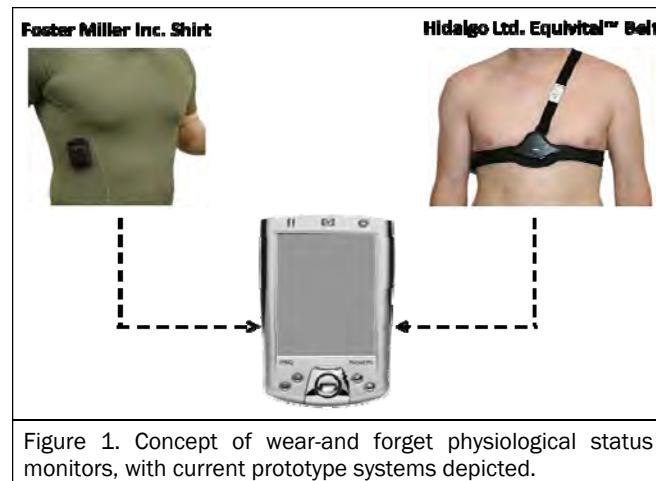


Figure 1. Concept of wear-and-forget physiological status monitors, with current prototype systems depicted.

The Army currently has received 2 prototypes of a physiological status monitor (PSM) that were developed under an Army Technology Objective and congressionally-funded programs. For the purposes of

combat casualty care, the PSM is designed to provide continuous monitoring of the electrocardiogram (ECG) and respiration rate. We recently tested both of these prototype systems for their ability to accurately measure R-R intervals (RRI, the interval between 2 R waves, derived from the ECG) and respiration rate during central hypovolemia. Briefly, healthy human volunteers were exposed to lower body negative pressure (LBNP), which we and others have demonstrated to be a reliable and reproducible experimental model of hemorrhage that can be performed in conscious humans.^{9,16} Measurements of RRI and respiratory rate from both of the prototype systems during hypovolemia were compared with those derived from a standard ECG and capnograph. Results from these experiments demonstrated that both prototype systems reliably measured RRI; while the Hidalgo belt also measured respiration rate with high fidelity, the Foster Miller shirt tended to underestimate the true respiration rate (Figure 2). In parallel with the laboratory experiments, both prototypes were also tested under field conditions during US Army Ranger training at Fort Benning, Georgia, in 2008. During a 2-day field test, the prototypes were evaluated for their ability to capture data as well as for their wearability and comfort. While data capture was acceptable from the Foster Miller shirt, there were some synchronization problems between the Hidalgo belts and the personal data assistant, resulting in a loss of data. Furthermore, there were complaints of chafing and discomfort from data capture devices that were placed on pressure points under the body armor with both prototypes. Clearly, further end-user testing under different environmental conditions will be required before either the current prototype or new systems are proposed for fielding.

WILL CURRENT PSM MEASUREMENTS AID REMOTE TRIAGE?

Making the assumption that wearability and data capture issues can be overcome with further development, the question becomes whether the information provided by the current PSM prototypes will provide sufficient clinical information to properly assess the status of a wounded Soldier beyond that of being alive or dead. Unfortunately, elevated heart and respiration rates resulting from hemorrhage in a wounded Soldier may not be distinguishable from elevated heart and respiration rates in a Soldier actively participating in a military maneuver or

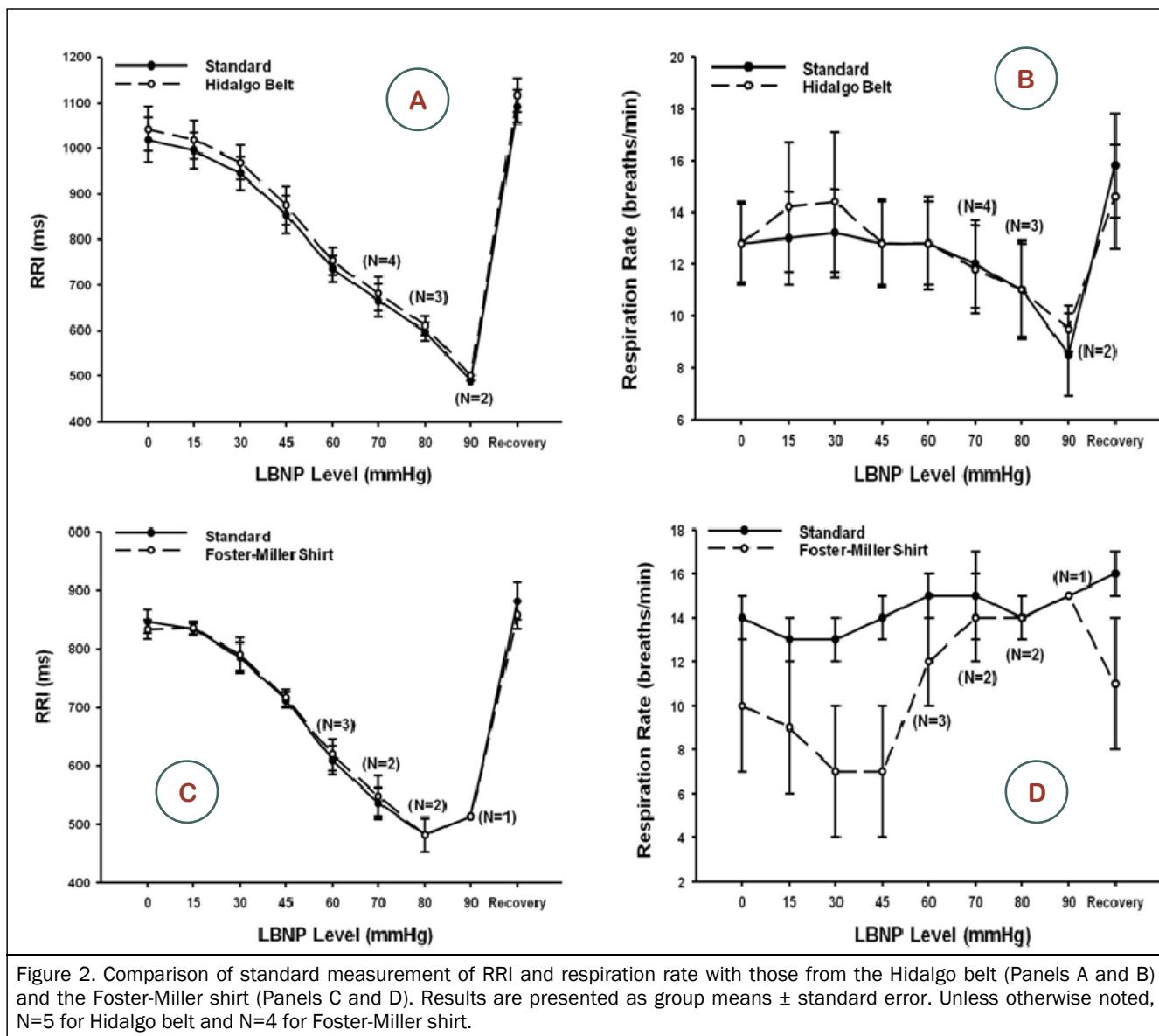


Figure 2. Comparison of standard measurement of RRI and respiration rate with those from the Hidalgo belt (Panels A and B) and the Foster-Miller shirt (Panels C and D). Results are presented as group means \pm standard error. Unless otherwise noted, N=5 for Hidalgo belt and N=4 for Foster-Miller shirt.

firefight. However, the investigation of naturally occurring rhythmic fluctuations in RRIs obtained from the ECG (ie, heart period variability (HPV)) underscores a multitude of feedback control mechanisms that may lend insight into normal and abnormal physiology, such as reduced blood volume resulting from severe hemorrhage. Since the first suggestion in 1963 that HPV might be useful for clinical monitoring of patients,¹⁷ this field has literally exploded, with indications that HPV monitoring might provide useful diagnostic information for such chronic disease states as cardiac diseases (eg, myocardial infarction, congestive heart failure), sleep apnea, diabetes, and renal failure.¹⁸ In fact, a PubMed search

performed in October 2010 on the term “heart rate variability” revealed more than 13,000 published papers. Despite this interest, these techniques have not yet been widely implemented into clinical practice or monitoring devices.^{19,20}

In the laboratory environment, frequency-domain analyses of HPV have been used extensively to explore human autonomic cardiovascular rhythms, especially as they relate to maintenance of steady-state hemodynamics through activation and inhibition of the autonomic nervous system. Spontaneous fluctuations in intervals between ECG R waves (ie, R-R intervals) around the respiratory (high) frequency (HF) are

known to be mediated by parasympathetic neural activity,²¹ while oscillations occurring at frequencies lower than respiration (LF) are thought to be mediated by both parasympathetic elements and sympathetic modulation of vascular resistance.^{22,23} Furthermore, HF spectral power decreases progressively (ie, parasympathetic withdrawal) during reductions in central blood volume and is inversely associated with sympathetic activation, demonstrating the expected shift in sympathovagal balance during central hypovolemia.^{24,25}

Based on this understanding, we first investigated whether frequency domain metrics of HPV would provide predictive power to discriminate between trauma patients in the prehospital environment who subsequently lived or died. To test this hypothesis, we measured HPV from ECG data collected during prehospital transport of civilian trauma patients who sustained blunt or penetrating injuries leading to hemorrhage.²⁶ RRI data were collected between 45 and 90 minutes after injury, while the average time of death was 9.5 hours in those patients who were nonsurvivors. The results indicated that patients who died had statistically higher RRI HF/LF ratios than those patients who lived. In a subsequent analysis, these results were verified in a larger cohort of patients that included more head and blunt injuries.²⁷ These initial analyses indicated that alterations in RRI HF/LF might be early markers of patient survival and thus provide clues for development of PSM-based algorithms to assist the combat medic with important remote triage decisions, particularly in a mass casualty scenario. Subsequently, Batchinsky et al²⁸ extended these observations to demonstrate that loss of RRI complexity (using nonlinear analysis of RRI to produce entropy and fractality measurements) was associated with subsequent mortality. Finally, loss of RRI variability and complexity was shown to be associated with the administration of a life-saving intervention (LSI) in data taken from trauma patients during the prehospital phase of care.^{29,30} Recently, RRI complexity metrics have been specifically advocated for use in remote triage applications.³¹ It should be noted, however, that in the majority of these studies demonstrating an association between HPV and either the administration of a life-saving intervention²⁹ or eventual mortality,²⁶⁻²⁸ at least one easily obtainable standard vital sign (eg, Glasgow Coma Scale motor score) also distinguished the 2 groups of patients (eg,

LSI vs no LSI, lived vs died). It was therefore unclear whether complicated calculation of a HPV metric would provide “added value” in enhancing triage capabilities over standard vital signs, particularly in situations in which the medic either had physical access to the patient or had radio communication that could be used to ascertain the patient’s ability to respond (ie, Glasgow Coma Scale).

The application of HPV for combat medic decision support has several attractive features, including: *a*) it can provide *remote* and *continuous* monitoring from a sensor system that can be worn by every Soldier; and, *b*) it can utilize a simple ECG signal provided by the current prototypes of PSM. While we^{26,27} and others²⁸⁻³¹ had initially used group mean analysis for determination of HPV utility, several important questions remained before realistically proposing the use of HPV metrics of any kind for remote triage of *individual* Warfighters or, for that matter, clinical monitoring of individual patients. For example, what are “normal” values for HPV metrics and are these reproducible in the same subject? What are technical requirements for valid calculation of HPV metrics? Are alterations in HPV metrics specific only to loss of central blood volume? Do HPV metrics track central hypovolemia in any given individual? In our further work, we systematically sought to answer these questions by determining whether HPV metrics are of use in tracking hemorrhage in individual patients, and whether responses of HPV metrics are specific to hemorrhage rather than to other combat stressors such as physical activity.

To answer the question of whether HPV metrics would track blood loss in individuals, we first determined intersubject and intrasubject variability in resting human subjects during the same experimental session to determine normal values and their reproducibility.³² While some of the complexity metrics (but not the time and frequency domain metrics) displayed reasonably low (coefficient of variation (CV)≤8.5%) intersubject variability and high (CV≤8.9%) reproducibility in our study, recent work from Tan et al³³ demonstrated that these metrics *a*) are not reproducible within individuals during different experimental sessions; and *b*) do not reliably reflect autonomic mechanisms responsible for HPV. The authors therefore concluded that caution is warranted in using these metrics as diagnostic tools.³³ In

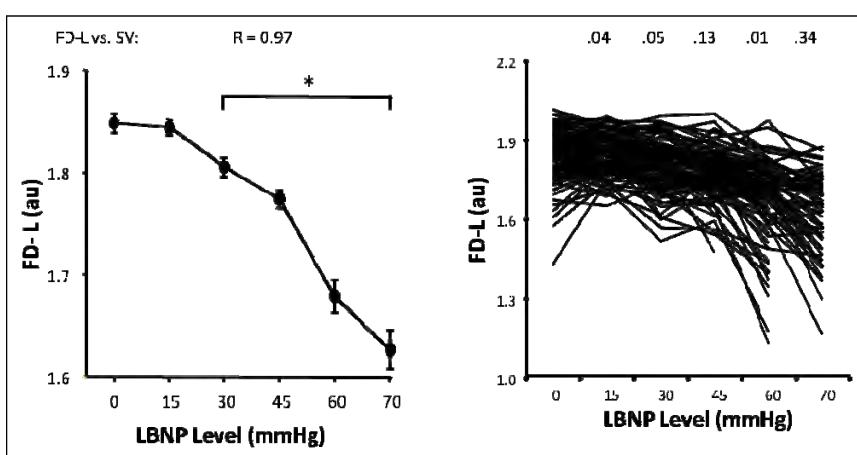


Figure 3. Left panel, group means for change in a representative HPV metric (fractal dimensions by curve length, FD-L) during LBNP. Right panel, individual trajectories for the same metric during LBNP. N=101. R values are correlation coefficients between FD-L and stroke volume (SV) for the group means as a whole during LBNP (left panel) and for individual changes in FD-L and SV at each LBNP level (right panel). Modified from Ryan et al.³⁴

agreement with the conclusions of this study, we found that, while group means of HPV metrics are highly correlated ($|r| \geq 0.87$)* with stroke volume (an index of central blood volume) during progressive reductions in central blood volume, analysis of the individual trajectories for HPV metrics demonstrated poor and inconsistent correlations ($|r| \leq 0.49$) with changes in stroke volume at the individual subject level (Figure 3).³⁴ From these data, we concluded that the HPV metrics do not reliably track individual reductions in central volume in the controlled laboratory setting and therefore may not be useful, even in trending analysis, in monitoring hemorrhagic injuries in individual patients.³⁴

In further analyses using real world data, we determined that 36% to 52% of trauma patients undergoing helicopter transport to the hospital demonstrate the presence of at least one ectopic beat within their ECG record,³⁵ valid determination of HPV metrics requires ECG waveforms that are free of noise and ectopic beats.³⁶ When the percentage of ECG waveforms rendered unusable by the presence of electromagnetic noise from patient movement or electrical interference is added, these limitations potentially exclude between 48% and 74% of prehospital trauma patients. On an individual basis, HPV measurements could therefore only be applied to approximately 26% to 52% of trauma patients.³⁵ For

* $|r|$ indicates the absolute value of the correlation coefficient.

remote triage applications, it might be anticipated that electromagnetic noise due to movement might produce an even larger problem. Finally, we determined whether HPV metrics provided added value to the ability to determine whether an individual patient would subsequently require a LSI. We analyzed ECG recordings collected on prehospital trauma patients with normal standard vital signs, testing the hypothesis that, if HPV metrics provided additional information above that of standard vital signs, these metrics would distinguish between those receiving a LSI and those that did not.³⁷ While group means of some of these HPV metrics statistically differed between the groups, there was inordinately

high (81% to 94%) overlap of individual patient HPV values between groups, suggesting that patients would have been incorrectly classified if HPV alone was used as a triage tool (Figure 4). This finding assumes even greater importance when considered in the context of remote triage, as ECG-derived metrics would be the only available resource in the absence of physical

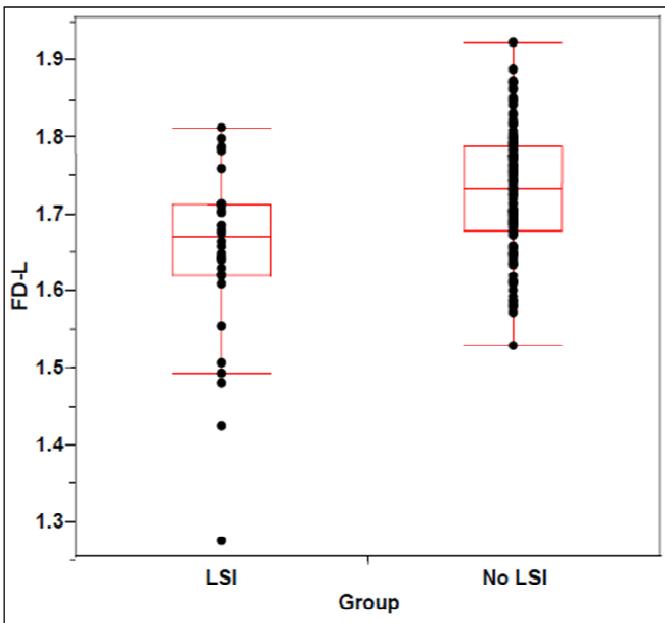


Figure 4. Box-and-whisker plot of fractal dimension by curve length (FD-L) demonstrating the high degree of overlap of individual values between the LSI (N=32) and No-LSI patients (N=127). Eighty-four percent of individual LSI patient values fall within the No-LSI range. From Rickards et al.³⁷

access to the patient using currently proposed PSM systems.

In order to effectively interpret an alteration in HPV metrics as suggestive of a casualty rather than a fighting Soldier in a remote situation, it is also necessary to distinguish the difference(s) in physiological responses under these conditions. To answer the question of specificity to hemorrhage, we tested the hypothesis that HPV metrics would be able to differentiate between subjects exposed to LBNP (simulating blood loss) or the same subjects undergoing moderate exercise.¹⁰ Figure 5 demonstrates that HPV metrics respond in a similar fashion during controlled laboratory experiments using LBNP vs exercise. Therefore, HPV metrics are unable to differentiate an active Soldier from a bleeding Soldier when the individual is not visible to the combat medic. While we used exercise as an experimental model to produce sympathetic activation and increase heart rate, it is important to note that other physiological stimuli occurring in combat Soldiers that increase heart rate (eg, anxiety, pain, heat or cold stress) might also be confused with blood loss if HPV metrics were used in a remote triage system. Indeed, Sacha and Pluta recently demonstrated that increases in heart rate of any etiology produce profound decreases in HPV metrics, purely for mathematical reasons because of the curvilinear relationship between heart rate and RRI.³⁸

To summarize, current remote triage wear-and-forget monitoring systems (ie, PSM prototypes) measure ECG and respiration rate. Certainly, this information could be useful in assessing whether a soldier is alive or dead following injury and the current prototypes therefore meet the objective criterion of life sign detection. An optimal remote triage system, however, would additionally provide valuable information a) that any elevation in heart rate, respiration, or other physiological indicator is a result of injury (specificity); and b) that could aid in determination of severity of injury (sensitivity). Such information could assist combat medic decisions such as the initiation of treatment and prioritization of evacuation. The data discussed above raise profound concerns that the implementation of HPV metrics into a remote triage system could provide this information. Therefore, we have redirected our focus to the development of a novel remote triage system that does not rely solely on ECG-derived metrics.

NOVEL MEASUREMENTS FOR REMOTE TRIAGE

If not HPV metrics, what should be measured to determine the presence and severity of hemorrhage in a remote triage system? From our laboratory studies, it is clear that stroke volume and pulse pressure (systolic minus diastolic blood pressure) decrease consistently with central hypovolemia, at least on a group mean basis.³⁹ As previously described, we performed a study in which the ability of HPV metrics to differentiate between a state of central hypovolemia simulating blood loss (via LBNP) and physical activity was ascertained.¹⁰ While HPV metrics could not reliably distinguish between these physiological conditions (Figure 5), we were able to identify that pulse pressure could differentiate the conditions of physical activity from LBNP (Figure 6). This was not an unexpected finding as pulse pressure (ie, systolic blood pressure minus diastolic blood pressure) tracks stroke volume, which increases with exercise⁴⁰ and decreases with LBNP.^{34,39} Hence, both stroke volume and pulse pressure could be reasonable candidates for determination of central hypovolemia during hemorrhage.

Currently, however, the only portable methods of measuring ambulatory blood pressure (and thereby deriving pulse pressure) or stroke volume are cumbersome and restrict movement and dexterity. Ambulatory blood pressure monitors, for example, use inflatable, restrictive cuffs around the upper arm or fingers in order to make blood pressure measurements. Additionally, for technical and comfort reasons, the majority of these monitors cannot take measurements continuously, with most providing output once every 3 to 5 minutes. Clearly, current noninvasive blood pressure systems are not practicable for use in remote triage systems.

Recently, the emergence of artificial intelligence technology has offered a potential solution to this issue. By definition, this scientific discipline designs algorithms that allow computers to evolve behaviors based on empirical data (eg, from sensors). In essence, the algorithms can “learn” to solve problems, and therefore show promise as being able to predict in time the point of cardiovascular decompensation in individuals subjected to central hypovolemia.⁴¹ Using this technology, machine-learning algorithms can be developed that learn to recognize patterns of responses in low-level physiological signals that are associated

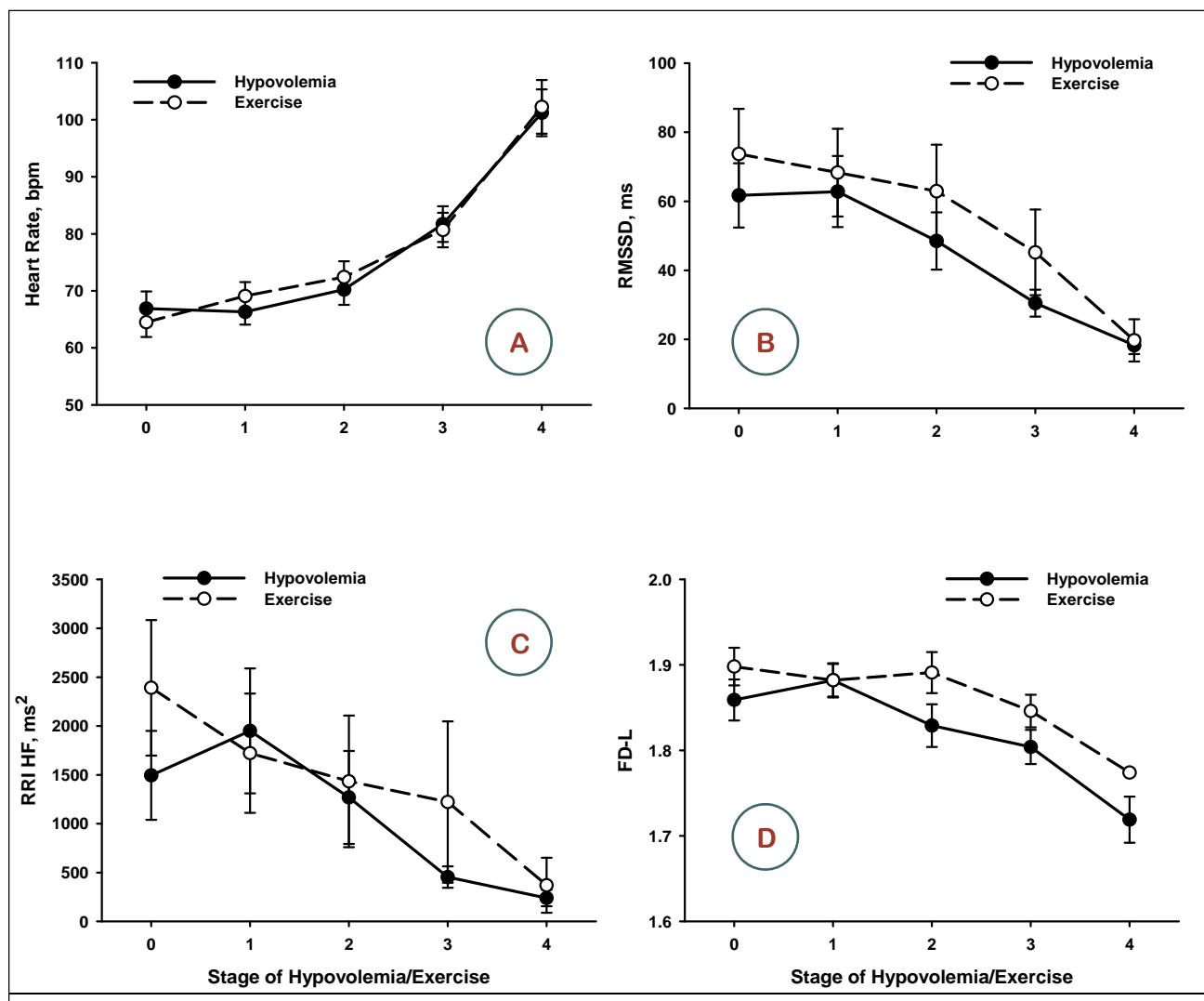


Figure 5. Heart rate (HR, panel A) and representative HPV responses to 5 stages of hypovolemia induced by LBNP and 5 stages of HR-matched exercise. Time domain (RRI root mean squared successive difference, RMSSD), frequency domain (RRI HF) and nonlinear complexity (fractal dimensions by curve length, FD-L) HPV metrics are depicted in Panels B-D. Panels A and C are from Rickards et al.¹⁰; panels B and D are previously unpublished data (K. L. Ryan et al, 2010). N=12.

with changes in parameters that reflect volume status (eg, stroke volume or pulse pressure). As an example, a wearable, noninvasive monitor for the indirect measurement of energy expenditure has recently been developed (SenseWear Pro2 armband (BodyMedia Inc, Pittsburgh, PA); Figure 7, left panel). When placed in the designated location on the upper arm, this sensor system armband is able to detect the galvanic skin response, heat flux, and skin temperature. Using these 3 inputs, a proprietary machine-learning algorithm has been developed to track the response of pulse pressure to physiological stimuli. In our laboratory, preliminary data indicate the ability of the armband algorithm to track the progressive decrease in

pulse pressure with application of LBNP (Figure 7, right panel). As a result, there was a very strong linear relationship between conventionally measured pulse pressure via finger photoplethysmography (Finometer (Finapres Medical Systems B.V., Amsterdam, The Netherlands)) and the pulse pressure predicted by the algorithm ($R^2=0.9$). Furthermore, recent results indicate that the algorithm could predict actual pulse pressure or stroke volume values during either LBNP or exercise and that this algorithm was able to distinguish between LBNP and exercise with high ($\geq 92\%$) accuracy, sensitivity, and specificity.⁴² While preliminary, these results suggest that machine-learning technology may be a promising component of future re-

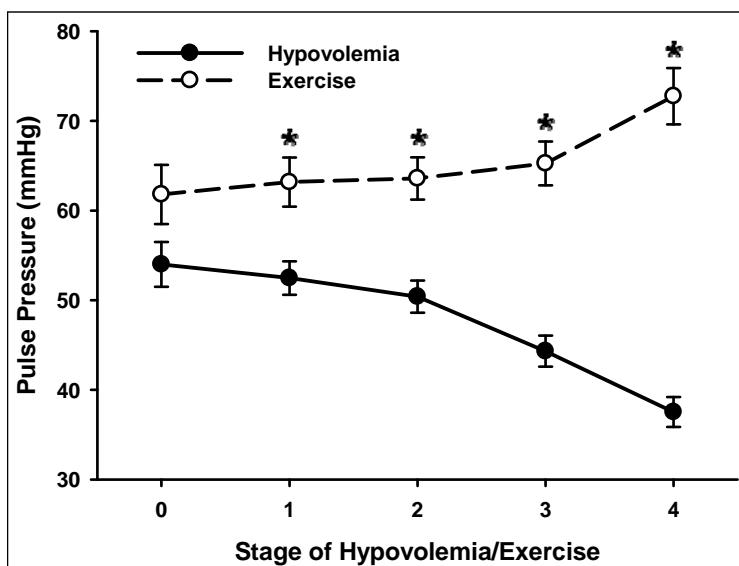


Figure 6. Pulse pressure response to 4 stages of LBNP up to -60 mm Hg and 4 stages of exercise. Asterisk (*) designates $P \leq .002$ between the LBNP and exercise conditions at that stage. From Rickards et al.¹⁰ N=12.

mote triage systems, as algorithms could be developed for distinguishing Soldiers who are active during combat from those who are hypovolemic due to traumatic hemorrhage. To date, all of these preliminary results have been acquired in a controlled laboratory setting with subjects who are not moving their arms appreciably. As development proceeds, it will be imperative to determine whether movement and other stressors (eg, dehydration, heat stress) produce measurement artifacts and, if so, whether these can be overcome. As always, field testing will be necessary to determine wearability and usefulness for the Warfighter.

It should be noted that, with the current configuration, implementation of an armband device in a remote triage system requires that the combat casualty have at least one upper extremity that is not severely injured. We therefore queried the Joint Theater Trauma Registry as to the likelihood that Soldiers in the current conflict would not meet this criterion. In Operations Iraqi Freedom and Enduring Freedom, only 6.47% of wounded Soldiers have presented with severe injury between

the elbow and shoulder on one arm that would preclude effective use of an armband device. Therefore, a remote triage system based on an armband device could be used after injury in at least 93.5% of Soldiers. Given the equal probability that injury would occur to any one side (ie, 50% chance of an injury to the right arm), a remote triage system based on a single armband device worn on one arm alone should be able to capture approximately 96% of Soldier monitoring.

STANDOFF REMOTE TRIAGE

In addition to wearable systems that would yield continuous physiological monitoring, it is also desirable to have a system for standoff triage of a wounded Soldier who can be visualized. Such a capability would allow a combat medic to ascertain the status of a wounded Soldier under fire before putting himself at risk, and would therefore decrease the probability of harm to the medic. In fact, a Navy corpsman presented a battle vignette from Operation Enduring Freedom at the US Army Institute of Surgical Research in 2009, in which he discussed how he cared for 17 wounded-in-action comrades while under fire. At the end of his presentation, he was asked for a “wish list” of capabilities that would help him care for wounded Soldiers. His highest priority was “a ray gun to check

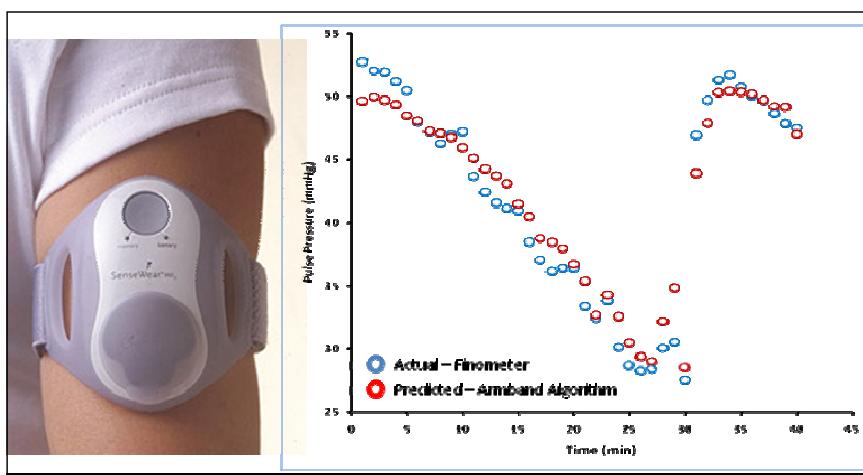


Figure 7. Left panel: current configuration of the BodyMedia SenseWear Pro2 armband. Measurements include galvanic skin response, heat flux and skin temperature. Right panel: comparison of values of pulse pressure predicted by a machine-learning algorithm using inputs from the BodyMedia SenseWear Pro2 armband with actual values measured by beat-to-beat finger photoplethysmography (Finometer). N=8.

out patients" (HM1 J. Torrisi, oral communication, 2009). Indeed, the authors have heard a number of high-ranking individuals within the medical departments of the various military branches express their wish for a "Star Trek tricorder."

At this point, the capability for standoff triage has not been realized. Both the US Department of Homeland Security and the Defense Advanced Research Projects Agency are currently funding, or have funded, initiatives aimed at developing this capability, using such technologies as laser Doppler vibrometry⁴³ and ultrawide-band radiofrequency radiation. It is quite conceivable that standoff technology could be developed to determine alive/dead status. If additional information concerning patient status is desired, the most promising signals to be measured will be those somehow associated with compensatory physiological responses to central hypovolemia. Measurement of such signals without contacting the body surface may be more challenging.

POTENTIAL ISSUES FOR REMOTE TRIAGE

It is clear that both combat medics and injured Soldiers would benefit from development of a capability for remote triage, whether in a wearable system or a standoff device. The above discussion focuses on our efforts to determine the best physiological responses to be measured by such a system during hemorrhage. Once developed, a number of other important issues must be resolved before fielding a capability in a battlefield situation. Clearly, any wearable remote triage system will have to be small, lightweight, rugged, and comfortable, and must not impede movement. In every war in recorded history, Soldiers have littered battlefields with gear that they felt was either not essential or diminished their mission performance. From this standpoint, solicitation of input from end-users is essential during the early developmental stages of these systems. Furthermore, remote triage systems will have to include algorithms that recognize when the physiological signals being collected have been corrupted by artifactual noise and are therefore not valid for accurate decision support. Additionally, any wireless radiofrequency communication produced by such a device will have to be integrated into the wireless communication network used on the battlefield. As part of this process, data transmission will have to be encrypted so that the location and status of an injured Soldier is not made

evident to enemy combatants. It will also be important to have any remote triage systems hardened to withstand common battlefield occurrences such as vibration, blast, and electromagnetic pulses, which can disable all electrical devices on the battlefield. Power supply issues should also be considered, with the ability to use commercially available small batteries (eg, AAA) for operation in remote areas without electricity. None of these issues are insoluble, with the key being integration of engineering and communication expertise early in the process of development of a system. Development of remote triage devices for battlefield use will also benefit from the recent profound commercial interest in development of similar devices for home healthcare applications. This is a very active area of research and development which will use similar technologies that could be adapted for applicability to combat casualty care use, and which could serve as predicate devices for FDA approval. Once a legitimate candidate for a wearable system is prototyped, it will also be essential to field-test the system to gather input on wearability and useability from both combat medics and Soldiers, the ultimate customers for the system.

CONCLUSION

When making a remote triage decision without access to the patient, the military medic must know if a Soldier is wounded or simply engaged in combat. To assist with such decisions, it has been suggested that the future Warfighter will be equipped with physiological monitoring devices that will have the capability to measure ECG and respiration signals. However, since our research demonstrates that the raw and derived measurements from these signals (eg, heart rate, HPV, respiration rate) will not differentiate an active Soldier from a bleeding Soldier, new technologies that provide measurements that specifically reflect bleeding trauma will be required for the situation in which the Soldier is not visible. Our research provides new evidence that technologies exist with the capability to obtain surrogate information about the continuous status of pulse pressure or stroke volume, and that such technologies could provide essential information to the combat medic on the blood volume status of the Soldier and the need for prompt medical attention. Providing accurate and reliable indicators of patient status from a remote location will potentially protect combat medics from unnecessary exposure to enemy fire, and assist in the timely triage

and evacuation of combat casualties. By producing new triage capabilities for use by the combat medic, the Advanced Capabilities for Emergency Medical Monitoring Task Area will also improve recognition of the need for early (prehospital) hemorrhage control and thereby reduce mortality on the battlefield.²

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Advanced Technology Development for Remote Triage Applications in Bleeding Combat Casualties

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Advanced Monitoring and Decision Support for Battlefield Critical Care Environment

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ABSTRACT

Automation and decision support systems are vital for improving critical patient care in the battlefield environment. However, advances in data management, sensor fusion, and decision support algorithms must be developed and incorporated into existing patient monitoring systems for this technology to improve battlefield patient care. This paper examines issues related to research and development of advanced monitoring and decision support systems for use both on the battlefield and in the civilian trauma environment.

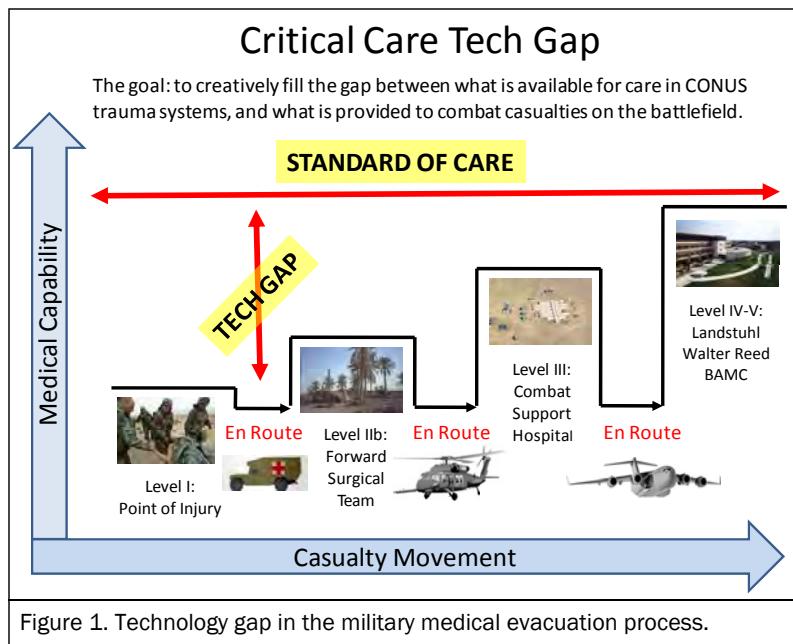
INTRODUCTION

Lack of information in the battlefield critical care environment continues to be problematic for adequate patient care. Insufficient actionable data on patient injuries means that care providers have to reevaluate the patient at each level during the evacuation chain. This problem becomes increasingly critical when injury severity requires immediate action to save the patient's life. When these issues are coupled with challenges related to treatment of injuries in a tactical, dynamic, and constantly shifting battlefield environment, effective patient care may become much more difficult and stressful on both patients and providers.

One of the main differences between military and civilian critical care systems is the military concept of patient evacuation via the casualty evacuation/medical evacuation systems. In many cases, Soldiers injured on the front lines may face a long series of treatment regimens starting at the level I echelon of care and potentially progressing to level V in the United States. This also includes advanced critical care during transport and en route care phases.

The complicated nature of the battlefield health care system creates a gap between state of the art trauma centers in the United States and trauma care facilities in the

lower battlefield echelons of care (Figure 1). This gap is driven by many factors which include not just lack of specialized care providers in the battlefield setting, but also logistical support issues related to providing expert care in an austere environment.¹ Even at the level V facilities, the degree of patient care may be driven to a large extent by the experience of the care provider. Previous studies have shown that the addition of expert providers, such as critical care intensivists, will improve overall patient outcomes due to the increased availability of expert care and help to mitigate problems with provider treatment variability.^{2,3}



One approach to reduce the patient care technology gap and improve patient care in the battlefield critical care environment is the use of advanced computer algorithms that provide care givers with additional information using decision support technology. These algorithms harness data derived from multiple sensors attached to the patient to derive solutions and recommendations for treatment of battlefield injuries. Specifically, the use of multivariate vital sign indices derived from high performance digital signal processing algorithms coupled with decision support technology that incorporate the knowledge and experience of expert care clinicians provides users with better indicators of patient status and actionable medical information tailored to the patient and injury type.

DECISION SUPPORT TECHNOLOGY FOR MEDICAL DECISION MAKING

The concept of computer decision support systems (CDSS) involves the use of computer algorithms that can process raw data into useful information while offering a platform for embedding the expertise and knowledge of advanced experts in a particular field. A clinical CDSS is further defined as a system specifically designed for use by clinical personnel by providing a software application that includes the clinical care rules, information processing, or know-how for the treatment or diagnosis of specific diseases or injuries. Previous studies have shown that a CDSS may improve patient outcomes by acting as an adjunct that provides additional knowledge, information, and recommendations to help providers at both the acute and routine phases of clinical care.⁴⁻⁶

The CDSSs can be broken down into different classifications or taxonomies based on their implementation and role within their environment.^{7,8} For the battlefield, 4 main taxonomies can be explored for use by clinical providers: data-driven, knowledge-driven, model-driven, and hybrid. Within these classifications, CDSSs can also be further refined based on their adaptive capability during use. Adaptive CDSSs will adjust the system recommendations based on responses from the patient on a case-by-case basis. This includes not only adjusting the value of parameters being controlled (ie, infusion rate), but also may include providing the user with different recommendations altogether (eg, switching from fluid

therapy to pharmacotherapy based on the patient's blood pressure response from a fluid challenge).

Data driven CDSSs are defined as computer algorithms designed to exploit the computational capacity of the computer system to analyze, test, and provide summaries of data that would normally be beyond the capability of a user to process. Increasing processing capacity of modern computer systems has facilitated the ability for algorithms to process large amounts of data that can be analyzed in very short amounts of time. The latest Intel (Santa Clara, California) processors running on today's personal computers have the capacity to process over 100,000 million instructions per second (MIPS) due to their fast clock speeds and ability to concurrently process multiple instructions for every clock cycle. Many new processors include advanced multicore designs that include the ability to execute instructions in parallel to improve application performance. These advanced architectures can be further enhanced by coupling them with advanced digital signal processing hardware for further performance improvements. Even processors available for newer mobile phones or mobile use have the ability to process over 1000 MIPS while significantly reducing power consumption and improving battery life. In terms of medical use, these capabilities allow today's computer systems to potentially analyze vast amounts of medical data for use by clinicians. Normally, these systems are not adaptive, but provide the user with grouping, trending, and multivariate fusion of medical and physiologic data that can be used as clinically meaningful information. Examples of data driven DSS applications include smart monitor alarms that use trending and triggers based on combinations of continuous multiple clinical parameters.

On the other hand, knowledge-driven CDSSs rely on the use of some type of built-in knowledge base to derive recommendations for users. These systems are also called expert systems or rule-based systems because they attempt to embed the knowledge of a subject matter expert (SME) into a computer application using sets of rules to represent the knowledge of the SME. The complete set of rules within the system makes up the knowledge-base for a particular problem or domain under which the CDSS will operate. These systems can be designed for use by novice users working in a new environment or expert

users who may have use for a validation tool. Knowledge bases for most rule-based systems are represented as a set of rules containing “IF-THEN” statements that cover the different situations that occur during the use of the CDSS. Rules of this system have 2 main sections. For each rule, an IF section defines a testable condition that results in an action that must be processed further by the system or the user. This section results in either a true or false condition which defines if that rule gets examined and executed by the system. The THEN section defines an action that occurs should the IF section be true. For example, a subset of a resuscitation CDSS may have rules such as the following:

- IF patient radial pulse is weak, THEN get the patient blood pressure.
- IF patient blood pressure is below 90 mm Hg, THEN give 1000 ml bolus of normal saline.

This type of CDSS normally includes an inference engine to process the rules within its knowledge base and choose the appropriate actions based on which rules are true. In many CDSS where the number of rules is small, the inference engine can be as simple as a search method that executes the rules sequentially. However, when the system is composed of large numbers of rules, the possibility exists that 2 or more rules may have conflicts with each other (ie, rule 1 suggests the fluid is turned down while rule 2 suggests the fluid is turned up). In these cases, a more complex inference engine is needed, not only to optimize the processing of all the rules, but also provide deconflicting solutions in cases where actions from different rules contradict each other. The Rete algorithm is one example of a commonly available inference engine algorithm for rule execution.⁹

Model-driven CDSS systems use internal mathematical models to determine or predict the behavior of the underlying operational domain space. A set of mathematical equations are used to define how aspects of the environment will behave under a given set of conditions. Users provide the system with parameters that the model will use to predict the behavior of the environment and use the results to generate a recommendation. For example, a resuscitation system for guiding trauma resuscitation may have an internal model of the blood pressure response to a given level of fluid, patient weight, age, and height. If a patient has a low blood pressure, the system can use that

information to determine the amount of fluid normally necessary to bring the patient to a higher and more acceptable blood pressure. Using this approach, the effectiveness of the system depends on the accuracy of the underlying model. For medical applications, many physiological changes may not be fully understood and use only approximate equations to model the fundamental factors associated with the process. These systems are commonly used in feedback control and closed-loop devices that use the response of the patient as feedback to adjust a patient care device. Closed-loop pain sedation is an example of this type of system.

In many cases, the use of machine learning or artificial intelligence technologies can be coupled with model-based systems to improve their performance in situations where the model response is not well known, or in cases where traditional statistics-based multivariate analysis does not provide a good fit. Several technologies have been explored for use in medical CDSS, including Bayesian decision trees, artificial neural networks, and support vector machines. These approaches provide ways for the system to reason based on uncertainty and limited knowledge of the environment, and generate a probability distribution used to model the resulting problem.

In battlefield critical care, CDSSs not only have to provide relevant clinical information, but also have to meet stricter requirements for use and deployment in a high conflict environment. These additional requirements include:

- Mobility. The CDSS may have to be carried by medics or used in facilities that are not in a fixed location. CDSS implementation, therefore, has to be as compact as possible given the potential use within the battlefield.
- Reliability. Use of a CDSS in this environment requires higher reliability to withstand deployment across vast geographically dispersed and austere environments in addition to having to operate in extreme temperature ranges.
- Ease of use. Human factors play an extremely important role when very limited training and/or usability information is available on the CDSS. Design of an intuitive graphical user interface is paramount in creating a system that is usable by military health care providers.

Examples of CDSSs under development for use in military environments include the US Army Institute of Surgical Research Burn Resuscitation Decision Support System (BRDSS). This system was developed to optimize fluid resuscitation of acute burn patients from point of injury providing recommendations for fluid titration during the initial 48 hours postburn. Importantly, the user may accept or modify these recommendations based on clinical judgment. Each hour on the hour, users provide the system with current infusion rates, urinary output for the last hour, and whether the patient is hemodynamically stable. The system uses a model-based CDSS algorithm to estimate the appropriate fluid rate for the following hour to maintain the urinary output within acceptable levels and keep the patient in optimal fluid balance. The system provides a mechanism for assisting the nonburn-care provider in the field with the ability to more effectively resuscitate a patient with acute burn. Additionally, the BRDSS provides an adjunct to reduce interprovider variability found when resuscitating patients using standard approaches.

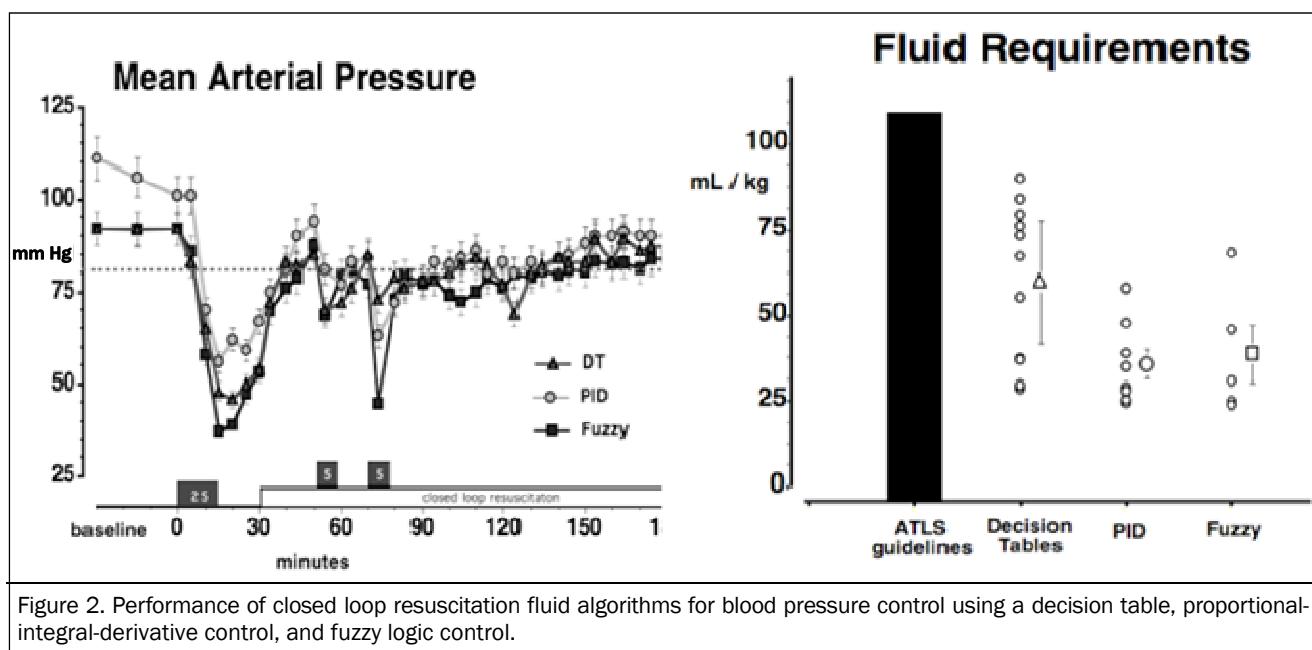
Another example of a CDSS is the closed loop fluid management system being developed by the University of Texas Medical Branch, Galveston, to provide medics and far-forward personnel with fluid recommendations during trauma resuscitation. Closed-loop fluid therapy has been studied in extensive animal research and most recently in human volunteers

subjected to hemorrhage. Using both normotensive and hypotensive target levels of blood pressure, closed-loop control was shown to effectively and efficiently resuscitate sheep subjected to uncontrolled or multiple hemorrhage protocols.¹⁰⁻¹² The left panel of Figure 2 shows the effectiveness of blood pressure maintenance with closed-loop titrated delivery of lactated Ringer's in conscious sheep during multiple hemorrhages of 25, 15, and 5 mL/kg. Groups compared used control algorithms based on a nonlinear decision table, proportional-integral-derivative (PID), or fuzzy logic. The right panel of Figure 2 shows the fluid requirements of 6 animals per group, as well as the 3:1 volume needs of standard of care therapy. Note the volume savings of closed-loop versus standard of care, and the greater volume savings with the more sophisticated PID and fuzzy logic algorithms.

These examples show the potential for improvement using CDSSs coupled with feedback and control designs. Future work will require testing of these systems in clinical trials that may elucidate further improvements of using this technology on injured patients.

DATA COLLECTION FOR CDSS DESIGN AND DEVELOPMENT

Data collection is an integral aspect of patient care and has evolved tremendously throughout the past century in the American hospital system. Additionally,



adequate data availability is critical for design, development, and operations of CDSS. In order to develop and implement accurate CDSS control rules and/or models, appropriate data have to be collected and analyzed for use during the algorithm development phase. Additionally, these data provide users ability to track diseases, healthcare trends, and epidemiological patterns of diseases, and have become an invaluable complement to the healthcare industry allowing healthcare providers to note trends and improve health outcomes. However, though most hospitals with a trauma center collect data through a data system or registry, a standardized or universal data collection system does not exist.

To address the problems with current trauma databases, there have been ongoing studies to improve handover of critical trauma patient information by identifying problems that hinder accurate data transfer. There has been research focused on maximizing handover of patient information between paramedics and the receiving staff in the emergency department.¹³⁻¹⁵ Evans et al noted that only 75% of the prehospital setting information was documented and, even worse, only 67% of data was documented in the in-hospital handover. Moss determined the most commonly missed variables during handover of a trauma patient were: prehospital hypotension, Glasgow Coma Scale (GCS) score, heart rate, blood pressure, and respiratory rate.¹⁴ Perhaps the solution to these issues is the implementation of what the military has used in its research. Not only is there a better way to transfer the data from paramedic to emergency room team, perhaps there are better variables to evaluate and analyze to obtain a more accurate picture of the severely injured patient. The researchers at the Army Institute of Surgical Research use data from the Trauma Vitals System for storing data of the trauma patient from the point of injury until arrival to the trauma center.¹⁶

Holcomb et al explored parameters in the prehospital setting which assist medical personnel with trauma patient triage to a trauma center for further lifesaving interventions (LSIs).¹⁷ The main physiologic signs found to significantly affect the need for LSIs were the GCS less than 6 and systolic blood pressure (SBP) below 90. When both GCS and SBP were abnormal, 95% of the patients required LSIs. Holcomb et al proposed the need for specific physiologic data analysis in the prehospital setting to discriminate patients who require LSI versus those who do not. With this in ef-

fect, trauma centers, whether military or civilian, will become more efficient in the care of trauma patients.

Unfortunately, as previously discussed, GCS and SBP often fail to make it past handoff from paramedics to the emergency room/trauma team. In a separate study, Holcomb et al¹⁷ also reviewed prehospital diagnostic and monitoring techniques which may best predict the need for prehospital LSI in nonhead-injured trauma patients. They had hypothesized that the addition of more automated systems during the treatment phase would increase the ability to predict if a patient required LSI.¹⁷ Holcomb et al proceeded to collect data from 3 distinct groups. All vital sign data collected among the 3 groups were stored and retrieved in the Trauma Vitals System. Group 1, the manual group (MG), contained only data that did not require instrumentation to obtain, ie, palpable pulse (radial, femoral, carotid) and either the motor or vocal component of the GCS score. Group 2, the semiautomated groups (SG), had all variables present in MG as well as vital signs that required minimal instrumentation. SG incorporated the eye component of the GCS and oxygen saturation as measured by pulse oximetry values. Group 3 was fully automated (AG) in data collection and included all variables from Groups 1 and 2, as well as noninvasive blood pressure, heart rate, end-tidal carbon dioxide, and respiratory rate.¹⁷ In the multivariate analysis of Groups 1-3, the variables with the best predictive power for prehospital LSI in the MG were radial pulse along with the verbal and motor components of GCS.¹⁷ The only variable SG had different than the MG was the GCS eye component instead of verbal. Review of the AG demonstrated that the addition of all automated vital signs did not statistically improve the area under the curve for the receiver operating characteristic curve in predicting prehospital LSI.¹⁷ Holcomb determined that in an area where it is not possible to have the more complex electronic equipment for vital signs, such as in a combat zone or mass casualty event, one can reasonably predict the need for prehospital LSI using radial pulse and both the verbal and motor components of GCS.¹⁷

In a retrospective study, McManus et al¹⁸ used the quality of prehospital radial pulses to estimate SBP, and also evaluated it as a method to rapidly triage a trauma patient. This study is similar to Holcomb et al, but McManus further characterizes the radial pulse in his patient evaluation. Pulse character as a marker for trauma triage is an important concept in environments

where the ability to obtain a SBP is difficult or impossible secondary to time constraints, unavailability of equipment, and/or a noisy/shaking field environment. Subjects in this study were separated into 3 groups. Paramedics involved with the helicopter teams were trained to identify the pulse as normal (strong, easily palpable), weak (palpable but difficult to find), or absent (no pulse). On review of the records, all patients with head injuries were excluded, as well as those with absent pulse as they were classified dead on arrival. To mimic the casualties seen in a combat environment, only patients from 18 to 50 years of age were included. In addition to radial pulse data, other variables collected were ones that could be rapidly assessed in a field environment without instrumentation: age, respiratory rate, capillary refill time, GCS, and gender. McManus et al completed a classification and regression tree analysis to predict the SBP. For patients with a weak pulse, the odds of mortality was 15.2 times greater than for those with normal character pulse. A weak pulse correlated with a mean SBP of 99.8 mm Hg, whereas a normal pulse correlated with a mean SBP of 128.7 mm Hg. After these numbers were obtained, the patients were split by age for those 39 years or older, and those younger. Subjects who had normal pulse and younger than 39 years of age had a mean SBP of 126.3 mm Hg, and those aged 39 years or older, 134.2 mm Hg.¹⁸ The older age group was further split based on the initial respiratory rate, either more than 31.5 breaths per minute, or less than that rate. The group with more than 31.5 breaths per minute had an average SBP of 104 mm Hg, and those with the lower rate had an average of 139 mm Hg.¹⁸ The results indicated that pulse character is highly sensitive as a predictor for SBP, but not specific. Most of the subjects with weak radial pulse were noted to have low SBPs, however, not all those with normal pulse characters had normal SBP as older subjects with higher respiratory rates had low SBPs.¹⁸ McManus et al showed that mortality was 29% in nonhead-injury patients with a weak radial pulse and only 3% for those with normal pulse character. Additionally, those with the weak pulse character were 5 times more likely to be admitted into the intensive care unit. Using pulse character, SBP could be approximated for rapid assessment and triage in trauma patients, as well as partial prognosis of their outcome.¹⁸

The Army Institute of Surgical Research has been active in the investigation of documentation

completeness and accuracy in the setting of prehospital/hospital data collection. Missing data not only hinders patient care but has been seen to delay LSI. Additionally, the missing values can be detrimental when records are reviewed for quality analysis or research. Current prehospital electronic monitors obtain vital signs such as oxygen saturation, blood pressure, and heart rate that are not as accurate in predicting patient outcome. A monitoring device should be small, lightweight, and with the ability for remote, wireless access and functionality which would benefit both civilian and military trauma providers.

ADVANCED MONITORING SYSTEMS FOR THE BATTLEFIELD ENVIRONMENT

As previously stated, lack of reliable information from the far-forward combat setting is one of the most important issues related to the use of vital signs monitors in the battlefield critical care environment. In order to help alleviate this problem, the Department of Defense has sponsored several advanced monitoring initiatives to provide products capable of capturing and analyzing data from patients in the field. A recent advancement in the data driven CDSS is the introduction of the wireless vital signs monitor, WVSM (Athena GTX, Inc, Des Moines, IA). The company recently received clearance from the US Food and Drug Administration to market the device, which is a compact, patient-worn wireless and/or wired monitor. This innovative piece of equipment automatically measures blood pressure, pulse rate, blood oxygenation, and other important critical vital signs from point of injury through transport to a treatment center. The WVSM device records up to 4.5 hours of these vital signs and is capable of wirelessly uploading this data to a personal digital assistant, mobile computer (tablet or laptop), and/or other computer system using a software program designed to search for and communicate with any WVSM device within range. The system uses a standard wireless IEEE 802.11 Wi-Fi signal, eliminating the need to reevaluate the patient at each level of medical care and providing continuous records of all vital signs recorded from the point of device operation. A rechargeable battery provides up to 7 hours of operation, depending on frequency of blood pressure measurements and status of Wi-Fi connection. To minimize tactical risk, all wireless functions and alarms can be toggled on and off as desired.

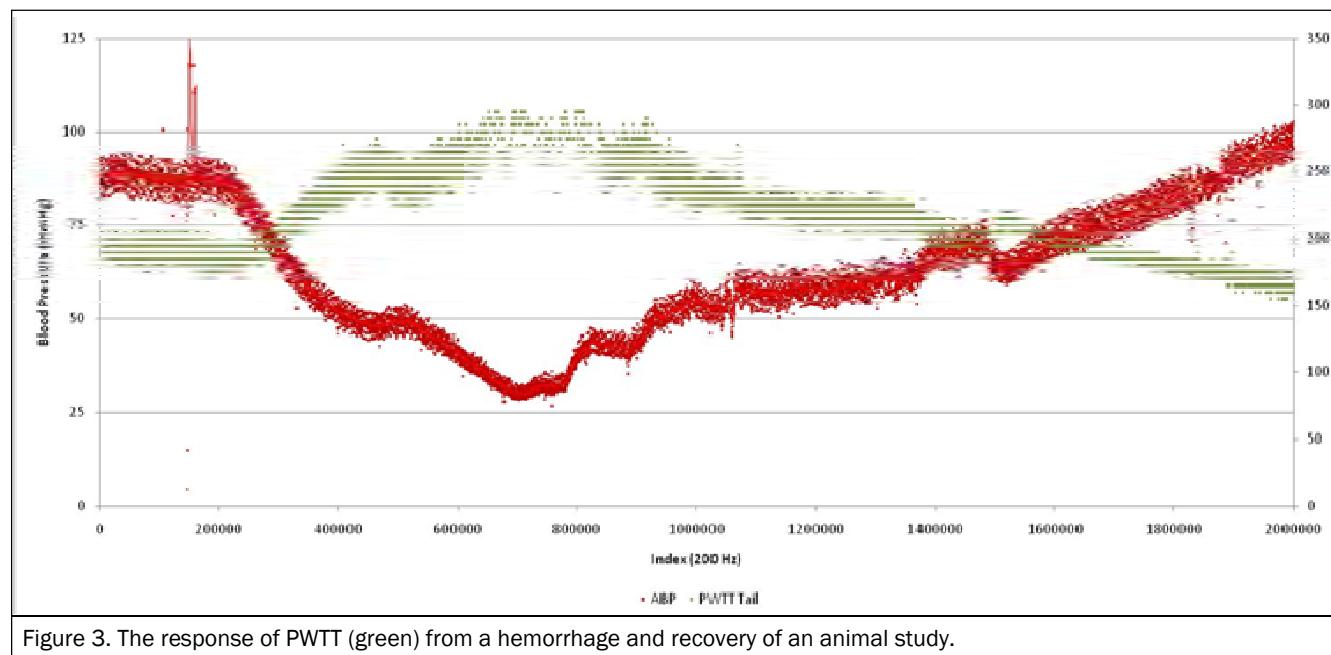
Designed for ease of use and transport to far forward situations, the WVSM weighs less than 16 oz and incorporates a standard blood pressure cuff, a reusable finger clip pulse oximeter, and a 3-lead electrocardiograph (ECG). In multiple injury situations, a color-coded and audible alarm system of critical parameters assists the caregiver in triage decisions, allowing simultaneous monitoring of multiple patients on the receiving station accessory software. The caregiver can quickly view each patient's status at the point of injury in order to accurately triage the casualty. As the patient arrives at the treatment center and comes within range of the facility's Wi-Fi network, the WVSM will automatically upload patient data to the treatment center's computer at the rate of one minute of history per second, providing a real-time view of all current vital signs and historical trends.

Additional equipment under development is a smaller vital signs monitor, the mini-Medic (Athena GTX, Des Moines, IA) system. The device is designed to be attached to the patient's forehead and provides the medic with a complete set of vital signs and smart alarms for patient monitoring. The "band aid" component, the forehead accessory, provides standard measures of pulse oximetry, heart rate, 3-lead ECG, and skin temperature, among other measures. A built-in near-real-time R-wave detector provides heart rate measures on the device for transmission to the receiving station. The monitor also includes a trauma

card where manual entry of mechanism of injury, drugs, and treatments can be entered.

In contrast to the WVSM, the size of the mini-Medic system prevents blood pressure measures using a standard cuff system. However, the device provides a measure of the patient's pulse wave transit time (PWTT) as a surrogate of patient hemodynamic stability. A proprietary algorithm is used to compute the PWTT and provide a real time patient blood pressure trend. With the continuous monitoring of PWTT, mini-Medic becomes increasingly sensitive to sudden changes in blood pressure, as shown in Figure 3.

Patient status is monitored via the Murphy Factor (Athena GTX, Des Moines, IA) smart alarm algorithm. The system provides the medic with decision support capability by combining all vital signs, trends, and pulse characteristics recorded by the monitor, and applying a multivariate sensor fusion algorithm that provides a combined index of the patient condition. Ratings are displayed as 0-1 in green, 2-3 in yellow, and 4-5 in red, indicating a patient who is in a normal, low priority, or high priority condition, respectively. The mini-Medic allows one medic to quickly deploy the sensing band-aids and begin triage decisions based on the easy-to-read handheld monitor displaying a color-coded numeric assessment. The medic can quickly and easily monitor up to 10 remote patients up to 100 meters away.



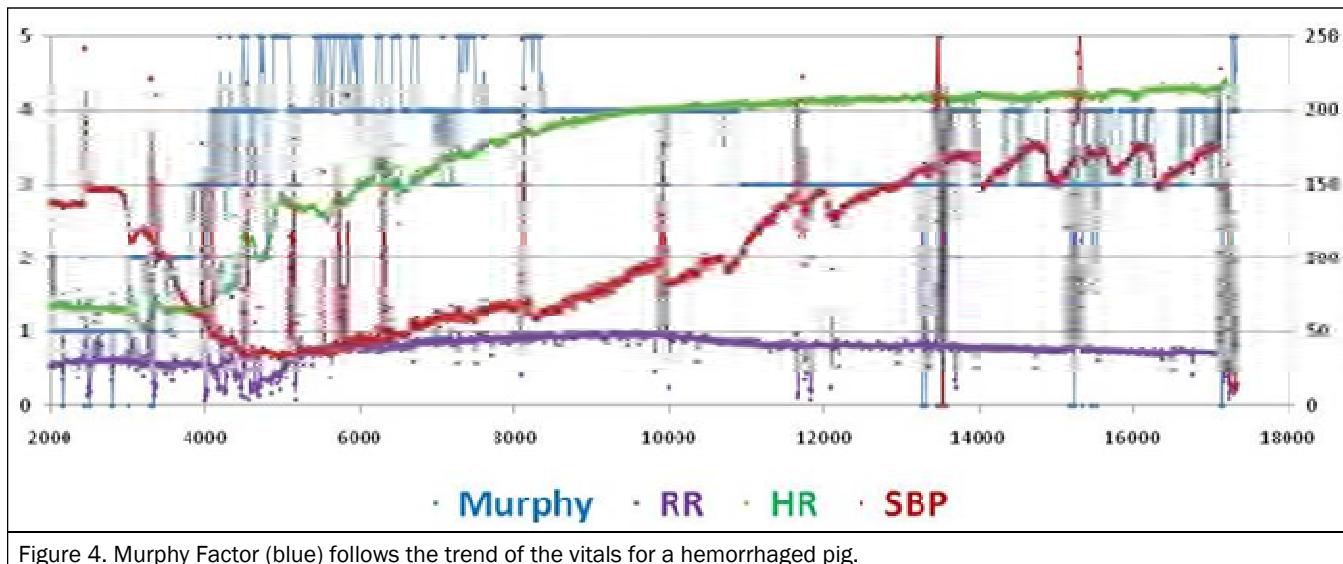


Figure 4. Murphy Factor (blue) follows the trend of the vitals for a hemorrhaged pig.

The algorithm used to display Murphy Factor has undergone extensive research to show strong correlation to other similar summary alarms. In a unique application of high mobility, stress, and motion, the algorithm automatically compensates for data dropout and missed data points by summarizing only what is known at the time, and never infers a value not present. An example presented in Figure 4 shows the Murphy Factor algorithm calculated on the vitals of a hemorrhage pig study. This example shows that the Murphy Factor jumps to a yellow and red level after the hemorrhage. In fact, since the algorithm picks up the quick drop in pressure the value jumps faster than the drop in actual BP. Then, as the animal stabilized and blood pressure measured posthemorrhage, the Murphy Factor lowered to a 3-4 range, still remaining elevated as the heart rate and respiratory rate are both elevated. In this case the dynamic nature of the measure is balanced by the fact that although the vital signs known are serious, the “patient” is stable.

To further assist the medic, a trauma card is included on the handheld monitor to allow the medic to enter data which is then stored on the patient’s forehead system. This allows all patient data including current readings, historical information showing trends, and medic entered information to remain with the patient from the point of injury through patient disposition. All of this information, along with current vital signs readings, can be wirelessly accessed upon arrival at the treatment center, either through the handheld device or from the band-aid accessory, for printout in the format of the Trauma Combat Casualty Care card.

CONCLUSIONS

Decision support and automation are critical technologies in the advancement of battlefield medicine. Nevertheless, several challenges remain to be addressed and resolved. Effective data collection, accurate models of physiology, and monitoring systems that can be deployed across all echelons of care need to be further developed and deployed. As computing power continues to increase, the availability of platforms for decision support technology becomes much more ubiquitous. However, there is still a need to tie computer systems engineering within an integrated framework for improving treatments and diagnosis that can be automated using state-of-the-art technology. These issues are currently being addressed through various research projects within the Department of Defense.

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Prehospital and Emergency Care Research at the US Army Institute of Surgical Research: Enabling the Next Great Leap in Combat Casualty Survival

LTC(P) Robert T. Gerhardt, MC, USA

ABSTRACT

Minimizing preventable death continues to be a primary focus of the combat casualty care research community, and of the Army Medical Department as a whole. Toward that end, tremendous successes have been realized in resuscitative surgery, critical care, rehabilitation, preventive medicine, and in our collective ability to project effective medical care into the most austere locations throughout the globe.

Innovation in the care rendered outside of theater hospitals or strategic air evacuation conveyances, however, has not kept the same pace. The US military experience in World War II, Korea, and Vietnam served as a prime source for the development of the tactics, techniques, and procedures which spawned modern civilian sector trauma care and emergency medical services. But this ascendancy was driven by the dedicated medics, corpsmen, physicians, nurses, and allied health practitioners from those conflicts who left the military for the civilian sector, leaving their replacements, in many cases, to repeat the same mistakes, and to relearn hard lessons that otherwise might have been assimilated had they been effectively captured and integrated into doctrine and training. A prime example of this phenomenon is the recent acknowledgement of the “en route care gap” existing in tactical medical evacuation.

The US Army Institute of Surgical Research (USAISR) and the Army emergency medicine community have made a significant commitment toward elucidating the requirements, capability gaps, and a way-forward in search of the development of an integrated prehospital combat casualty care system, nested within the Joint Theater Trauma System. This paper examines specific research programs, concept development, and collaborations with other Army, joint, and civilian center organizations which comprise the USAISR Prehospital and Emergency Care Research Program, including the Remote Damage Control Resuscitation initiative, Emergency Telemedical Direction of Role-I providers, Combat Medical Voice Documentation System, and establishment of the Remote Trauma Outcomes Research Network.

THE PROBLEM: PREVENTABLE DEATH ON THE BATTLEFIELD AND OTHER DEPLOYED SETTINGS

In the current conflict in Iraq and Afghanistan, the theater-wide case fatality rate (defined as the sum of the number killed-in-action plus the number died-of-wounds, divided by total number of battle casualties) approximates 12%.^{1,2} Of these unfortunates, perhaps one-third represent “potentially preventable causes of death,” excluding catastrophic central nervous system injuries, great vessel injuries, and massive burns.^{3,4}

Within this population of potentially preventable deaths, perhaps half die for lack of a life-saving intervention (LSI) performed within 10 to 20 minutes of wounding.⁴ LSIs include airway/ventilatory support, tourniquet or compression of accessible hemorrhage, and decompression of intrathoracic tension physiology, be it tension

pneumothorax, massive hemothorax, or a combination of both. Retrospective studies of the implementation of advanced practice medics and credentialed emergency care practitioners have likewise decreased case fatality from the reported 12% to approximately 6.7% and 7.1% respectively, citing primarily the association between early performance of LSIs with this survival improvement.^{2,5} Preliminary data from a retrospective analysis of military critical care paramedic-staffed Army air ambulances, with a survival improvement of roughly 50% in severely wounded service members (defined as injury severity scale greater than 15), provided further corroboration of these observations (LTC R. L. Mabry, oral communication, September 2010).

The aforementioned data support the contention that a capability gap exists in the scope-of-practice and clinical competency of prehospital combat casualty care pro-

viders, both among paraprofessional medics and corpsmen, and credentialed practitioners. Yet even were this capability gap to be bridged, there remains a sizeable subpopulation of preventable combat deaths resulting from the lethal combination of noncompressible truncal hemorrhage (NCTH), environmental effects, and protracted time intervals between initial injury and access to resuscitation and hemostatic surgery.⁶ In reality, once LSIs are performed and initial intravascular boluses of colloidal fluids are administered, the current prehospital combat casualty treatment algorithm is essentially exhausted.

Ultimately, the solution is to bring the casualty and surgical facility closer to each other. In lieu of that, it is theorized that were it possible to accurately identify the NCTH casualty, one might employ specific physiological and biochemical characteristics as well as tactical data to determine which casualties are at greatest risk for requiring massive blood transfusion, and the associated risks for coagulopathy, acidosis, and hypothermia.⁷ Further, if forward-deployable blood components were to become available, along with a mechanism for clinical oversight for their use, it might become possible to treat those conditions, forestalling the onset of this “lethal triad” as the casualty undergoes evacuation to an operating table in a condition that might improve their chances of survival.

TOWARD AN INTEGRATED COMBAT EMERGENCY MEDICAL SERVICES SYSTEM

Presuming the premises described above to be true, the next steps toward meaningful reduction in combat deaths would encompass improved clinical competence and advanced scope-of-practice for prehospital combat casualty caregivers, the accurate, timely and accessible acquisition of prehospital patient care records for both documentation and process improvement, and a technological solution for the initial temporization of casualties suffering from NCTH.⁸ All will require professional medical oversight, clinically-validated operating guidelines or protocols, and an integrated network of initial tactical medical care, medical evacuation with care continuing en route, and coordination with destination surgical facilities on a fluid battlefield.⁹ Arguably, this scenario represents the integration of prehospital care into the Joint Theater Trauma System (JTTS) in a manner analogous to the integration of prehospital care into civilian sector trauma systems. Another way of viewing this scenario is the image of a combat emergency medical services (EMS) system.¹⁰

While such a vision is notable for its audacity, it also presents a viable approach to integrating critical assets

within the Army Medical Department (AMEDD) and the Army as a whole toward the laudable goal of driving the rate of preventable combat deaths toward zero. These include the AMEDD Department of Combat Medic Training, the Army EMS Program Management Office, the Directorate of Combat and Doctrine Development, the USAISR, the Medical Communications for Combat Casualty Care Program Office, the US Army Aeromedical Center, and the Office of The Surgeon General, among others. Toward this end, the USAISR’s Prehospital and Emergency Care Research Program continues its labor to link doctrinal and training solutions with technology and clinical innovation.

REMOTE DAMAGE CONTROL RESUSCITATION INITIATIVE

Presuming they receive required LSIs and survive the initial postwound period, severely wounded individuals with continuing hemorrhage and delayed evacuation are more likely to die eventually due to the cumulative deleterious effects of NCTH—hypothermia, acidosis, and coagulopathy.⁴ The later conditions have become known as the lethal triad.¹¹ The damage control resuscitation paradigm employs selected use of blood products early in the course of trauma resuscitation in an attempt to prevent or mitigate development of these conditions.¹²

Blood product transfusion at Role-I (prehospital combat casualty care) is a concept not foreign to the Israeli and British conventional military medical communities, though it is administered exclusively by credentialed practitioners.^{13,14} In likewise manner, remote damage control resuscitation (RDCR) is a concept envisioned for use in the out-of-hospital setting in cases where severely injured patients with continuing NCTH face delays in evacuation to resuscitative surgical intervention. These delays may result from weather conditions, time and distance factors, and availability of evacuation assets in proximity to the patient. In the setting of conflict, additional causes of evacuation delay might include hostile action, prioritization of tasks required for mission accomplishment, and logistical constraints.¹⁵ In such cases, RDCR may provide a coherent diagnostic and therapeutic algorithm for early intervention in the out-of-hospital phase, with the objective of delivering optimized preoperative patients to the military trauma surgeon.

By projecting the concept of damage control resuscitation forward of the Role-II (forward surgical facility) or III (theater hospital) emergency medical treatment section, and building upon the Tactical Combat Casualty Care (TCCC) paradigm, RDCR might employ advanced monitors and point-of-care diagnostics to diagnose or predict NCTH during the tactical field care or tactical evacuation

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phases.¹⁶ Following this diagnosis, decision support devices coupled with emergency telemedical direction would provide the authority to employ advanced therapeutic agents by noncredentialed medics or corpsmen remotely. These agents might include lower volume intravenous colloid fluid infusion in the form of freeze-dried or spray-dried plasma. With the advent of field-deployable thromboelastography, it may also become possible to administer freeze-dried platelets, targeted procoagulants, such as recombinant Factor VIIa or activated prothrombin complex, or antifibrinolytics such as tranexemic acid. Eventually, hemoglobin-based oxygen carriers or even whole-blood substitutes might become available for employment in a future RDCR paradigm. If one accepts the premise that the employment of hospital-based damage control resuscitation may improve survival from 16% to 40% over standard trauma care, translation of RDCR into the Role-I setting may likewise yield encouraging results.

EMERGENCY TELEMEDICAL DIRECTION

Both conventional wisdom and recent data collected from the Iraq theater of operations imply an improved rate of casualty survival resulting from the presence of emergency medicine-skilled triage, treatment, and evacuation decision-making in the prehospital (health service support levels I and II) phase of combat casualty care.^{2,5} Despite the potential significance of these preliminary findings, the pool of military emergency medicine practitioners (physicians, emergency medicine specialty-trained physician assistants, and advanced practice medics) available to deploy with conventional forces is unlikely to increase for the foreseeable future, and their current force levels are inadequate to staff a preponderance of deploying combined arms battalions or even brigade combat team medical treatment teams.² As a result, alternative methods of exporting this expertise and procedural competency must be sought. Preliminary studies of EMS-style medical direction and of advanced treatment protocols for combat medics under the supervision of military emergency physicians appear promising.¹⁰ Preliminary investigations of emergency telemedical direction of primary care physician-led resuscitation teams in simulated casualty care scenarios, under the auspices of the Emergency Telemedical Direction of Role-I Providers Project, have also been shown to be feasible, and in an initial pilot trial, improved the rate of completion of LSIs from 56% to 100% (R.T.G. et al, unpublished data, 2010). The Army Institute of Surgical Research remains actively engaged in the investigation of emergency

telemedical direction as a primary mechanism both for enabling RDCR by forward-deployed practitioners, medics, and corpsmen, and for providing the legal and ethical authority for out-of-hospital blood product usage.

COMBAT MEDICAL VOICE DOCUMENTATION SYSTEM

Despite robust and accurate collection of patient care reports and clinical data initiated at forward surgical facilities (Role II) and theater hospitals (Role III), there remains a sparse record of such data collection in the prehospital combat casualty care setting (Role-I).^{*} This capability gap not only impedes patient care, but it also prevents meaningful process improvement, which has contributed materially to the static case fatality rate in the Role-I setting.

A combination of legacy documentation formats (written field medical card, form DD 1380), spotty Role-I casualty data documentation enforcement by battalion and brigade medical command structures, and a pervasive perception by many Role-II/III practitioners that data coming from Role-I providers holds little value, among other issues, set the conditions for failure in collecting this vital data. While there are isolated examples of success in collecting and processing Role-I data mainly from the Special Operations Forces setting, the majority of anecdotal reports from conventional forces in the field indicate that “completed” DA 7656/TCCC cards often contain incomplete data, and are often completed several hours retrospective to the patient care encounter.^{*} While retrospective patient care report completion is common in the civilian sector EMS community, the general practice is to complete and file these patient care reports within the immediate posttransport period, often while the ambulance is being restocked for return to service. Understandably, the concern in the case of delayed completion of prehospital casualty care records (PCCR) centers on recall bias, as well as difficulty in linking these records with their respective casualties as they wend their way through the casualty care and evacuation chain. Despite these obstacles, civilian sector experience in EMS data collection and research has demonstrated that timely, accurate, and relevant out-of-hospital clinical data can be collected.¹⁷ Furthermore, not only is it a medico-legal requirement in the civilian sector that these data be collected as part of the medical record, but that by collecting, de-identifying, collating, and analyzing it, we may improve both the emergency medicine system itself and the quality of patient care delivered by it.¹⁸ Clearly, our combat casualties deserve nothing less.

*Source: Joint Theater Trauma Registry, an internal military database not readily accessible by the general public.

Toward this end, USAISR initiated investigations into threshold solutions for bridging this Role-I PCCR capability gap.¹⁹ A rugged, hands-free, high-fidelity voice recorder was considered as an effective entry-level mechanism for capturing the PCCR data that compose the DA 7656/TCCC card, as well as follow-on treatment interventions at forward resuscitative surgery and during en route care. A prototype combat medical voice documentation system (CMVDS) is being developed under the guidance of USAISR, in cooperation with the Medical Communications for Combat Casualty Care Directorate and the private sector. The CMVDS device is composed of a recorder capable of capturing the human voice after filtering-out typical background noise which is ubiquitous on the battlefield, coupled to a data recording “sled” which allows near-immediate downloading of the recording, permitting the combat medical provider to retain a copy of the recording while sending the recorder itself with the casualty. After arrival at theater hospitals, it is envisioned that CMVDS would be downloaded by a trauma registrar, after which it may be manually transcribed, or processed via a natural language processing software application into a standard word processor file. Subsequently, the clinical data could be uploaded to medical records, registries, and for command and control purposes. A corresponding natural language processing software system capable of digitizing the audio files generated by CMVDS is also under development, with the objective of uploading PCCR data into an electronic medical record, and for populating the prehospital segment of the Joint Tactical Trauma Registry.¹⁹

REMOTE TRAUMA OUTCOMES RESEARCH NETWORK

In order to be successfully developed and actualized, the aforementioned RDCR paradigm will require clinical validation and demonstration prior to translation to the battlefield. It is widely acknowledged that prehospital research is difficult to conduct; the contemporary operational environment adds further complications in terms of protracted time periods from point-of-wounding to resuscitative surgery.^{15,17,18} Thus, the identification and development of a relevant and sustainable test bed for RDCR and related out-of-hospital trauma research was identified as a priority by USAISR.

The Southwest Texas Regional Advisory Council for Trauma (STRAC) is a robust and mature network of community hospitals, regional trauma centers, EMS units, and air medical transport organizations. It is affiliated with the Brooke Army Medical Center, USAISR, and the University of Texas Health Science Center–San Antonio. A preliminary review of interfa-

cility trauma transports within this network revealed numerous cases of transport time intervals from 40 minutes to an excess of 6 hours, often from outlying facilities without surgical capability. With the notable exception of hostile fire, an analysis of time-distance and environmental issues in this setting bore remarkable similarity to the contemporary operational environments in Afghanistan and Iraq. As such, the STRAC network was identified as a potentially optimal model for studying RDCR applications.

Recently, USAISR was awarded congressionally-directed funds to support the development of the Remote Trauma Outcomes Research Network (RemTORN) Project. The stated objectives of this program are to establish the physical and personnel infrastructure for the collection of both out-of-hospital (initial response and interfacility) and linked inpatient clinical data for trauma patients undergoing initial stabilization followed by transfer to the Brooke Army Medical Center or University Hospital, both level-I trauma centers; and to initiate observational studies of physiologic monitoring, coagulation status, injury severity, and en route care in anticipation of subsequent clinical trials of RDCR protocols. As this test bed matures, RemTORN is envisioned as providing the translational bridge for testing and proving the technologies, training interventions, and clinical guidelines that will enable the mitigation of NCTH, which will further decrease the rate of preventable combat deaths. Coincidentally, it is anticipated that RDCR interventions will also translate into civilian sector applications, particularly in such settings as rural EMS, austere/wilderness emergencies, tactical medical operations, homeland and overseas disaster response, and regionalized trauma networks.

BRINGING IT ALL TOGETHER

Rigorous scientific inquiry and integrated innovation at the Role-I level of the battlefield are relatively young and emerging concepts. While the obstacles and challenges are daunting, the potential dividends are equally substantial. To realize them will require innovative thinking, commitment, and substantial resources in terms of talent, fiscal support, and staff work. Collaboration with joint, interagency, and civilian sector partners from academia and industry will also be critical. Through our current initiatives and other cooperative efforts with AMEDD directorates and Navy and Air Force partners, the Prehospital and Emergency Care Research Program of the USAISR has sought to chart a coherent, relevant, and actionable roadmap for enabling the next great leap in casualty survival.

Prehospital and Emergency Care Research at the US Army Institute of Surgical Research: Enabling the Next Great Leap in Combat Casualty Survival

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Improving Role I Battlefield Casualty Care from Point of Injury to Surgery

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INTRODUCTION

Role I battlefield medical care is care provided in the prehospital environment outside of the forward surgical team and the combat support hospital. It includes aid delivered from the point of injury through the battalion aid station or brigade support medical company until the casualty is delivered to surgical care. Providers of casualty care at this stage include injured Soldiers themselves (self-aid), fellow Soldiers (buddy-aid and combat life-savers), combat medics, flight medics, battalion surgeons and physician assistants.

Historically, the Army Medical Department's (AMEDD) chief focus in wartime has been the provision of quality hospital-based and forward surgical care. During the current conflict, tremendous medical advances have been made that saved the lives of many Soldiers who would have died in other conflicts.¹ If a salvageable patient arrives alive at surgical care in the current conflict, the likelihood of survival is nearly 98%.² Yet 3 out of 4 deaths occur on the battlefield before reaching a surgeon, with as many as 28% of fatally injured Soldiers dying with potentially survivable injuries.³ Therefore, any significant future improvement in saving Soldiers' lives is most likely to occur in the prehospital setting. This will require a significant shift in AMEDD focus to emphasize the prehospital environment.

It is important to recognize that while the AMEDD trains medical providers, establishes doctrine, and develops medical equipment sets for the prehospital environment, line commanders are ultimately responsible for the medical care of their Soldiers on the battlefield. Yet busy combat arms commanders receive little training on how Soldiers die in battle and how they as leaders can best prepare their Soldiers to react to casualties. Instead, line commanders have relied on their "Doc," usually their battalion surgeon or physician assistant (PA), to advise them on medical

training and casualty care tactics, techniques, and procedures. This places great responsibility on the battalion surgeon or PA in terms of setting the example for clinical excellence in the line unit, as well as demonstrating competence in medical staff planning and execution.

The role of the battalion surgeon, PA, and combat medic are therefore central to the success of battlefield care and critical to the survival of wounded casualties. To advance the state-of-the-art, this article examines current military prehospital care policies and procedures and uses the highly evolved civilian emergency medical systems as a study of contrasts. It further proposes a comprehensive way to exploit advantages of the civilian system for the benefit of the US Army and, ultimately, battlefield casualties.

HISTORICAL PERSPECTIVE

Wars are "epidemics of trauma." These epidemics have historically leveraged advances in military surgical and trauma care that are often later applied to the civilian trauma setting. The most salient aspect of military prehospital medicine historically and today has been the rapid clearing of casualties from the battlefield. During the 18th and 19th centuries, exposure was the most prevalent killer of wounded Soldiers. Wounded Soldiers, especially those on the losing side, would often lie for days where they fell, exposed to the elements without water, food, or shelter.⁴ Officers and those who could afford medical care would hire surgeons to accompany them during the campaign or seek care on the local economy following the action.

Dominique Jean Larrey, Napoleon's surgeon, recognized that delays in evacuation increased mortality and suffering for the wounded. He developed horse-drawn "flying ambulances" to rapidly treat and evacuate wounded soldiers from the field.⁴ During the US Civil War, several scandals followed early battles

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after injured Soldiers remained on the field for days, with some left for dead and even robbed by ambulance drivers as they lay wounded. Public outrage enabled Dr Jonathan Letterman, medical director for the Army of the Potomac, to institute many sorely needed reforms, including the formation of a dedicated Ambulance Corps that would function similarly to Larrey's system. Letterman's reforms were adopted by militaries throughout world. The principle of rapid evacuation through "echelons of care" established by Larrey and Letterman is still the doctrinal model used by the AMEDD and most modern armies today.⁵

Modern warfare of the 20th century brought about more lethal weapons, such as precision artillery and machine guns, necessitating further dispersion of forces. Ambulances became mechanized. Specially trained corpsmen and medics were placed into combat formations for the first time to provide dedicated point-of-injury care. Medic training was rudimentary and traditionally had minimal involvement from physicians. It was thought that little could be done on the firing line other than basic skills, such as applying bandages and splints and carrying the patient to the aid station on a litter.

The Korean and Vietnam eras brought helicopter evacuation to the fore. Indeed, the icon of modern battlefield medicine in the United States is the Dust-off helicopter. The Dust-off epitomizes modern battlefield care in that an injured soldier can be whisked from the battlefield to surgical care within minutes of wounding. Military trauma systems built during Korean and Vietnam combat steadily increased the survival rates of wounded Soldiers.

In 1966, the National Academy of Sciences published *Accidental Death and Disability: the Neglected Disease of Modern Society*.⁶ This paper remarked that Soldiers wounded in Korean and Vietnam received better trauma care than civilians injured in automobile accidents in American cities. It noted that ambulances lacked standardization, equipment was inadequate, and ambulance attendants were often poorly trained. Millions of dollars in federal funding followed the publication of this paper, giving rise to our modern civilian emergency medical systems (EMS).

The end of the war in Vietnam saw the birth of the modern EMS and the formation of a new medical specialty, emergency medicine. Physicians, nurses,

and medics with significant combat experience demobilized and returned to the United States, bringing the wartime lessons learned from military trauma systems to the civilian sector.⁷ From the 1970s until today, civilian EMS and the practice of emergency medicine have flourished, advanced, and developed into a unique and distinct subspecialty of medicine with their own body of scientific research and specially trained providers.

The AMEDD's primary focus in the post-WWII period has been on operating fixed medical facilities and providing quality healthcare to its beneficiaries. Military healthcare providers are trained to the highest civilian standards. Military physicians, PAs, and nurses are all required to pass the same boards and certification and licensing examinations as their civilian counterparts. Their training takes place in a fixed-facility hospital or clinic environment. Military providers in training, particularly those attending uniformed service programs, often have "military-unique" medical education requirements. Because of the intensity of these programs and rigid accreditation requirements, the military unique training is necessarily provided at an introductory level.⁸

Newly minted physicians and PAs are then assigned as battalion and brigade medical officers. These providers are then responsible for unit medical training, readiness and staff medical planning, as well as providing care at the battalion aid station or projecting forward on the battlefield themselves during larger operations or mass casualty incidents. Predeployment medical training is required, but these courses are often just-in-time and occasionally deferred.⁸

It has long been a paradox of military expediency that the most junior and least experienced providers are the ones challenged to manage complex cases such as multiple combat trauma in a setting far from mentors or specialists.

The battalion PA has traditionally served as the mentor for the combat medic. The PA program was started by physicians at Duke University who saw a group of individuals with a tremendous amount of hands-on experience, but lacked formal training and recognition. These were the combat medics from the armed services who had served in Vietnam. These physicians began the first formal Physician Assistant Training Program at Duke in 1965. The Army's PA training

program began in 1971, with the first class graduating in July 1973.⁹ But the character of the Army's PA corps has changed since PAs became commissioned officers in 1992. Because of commissioning rules and education requirements, experienced enlisted combat medics are now rarely able to meet the prerequisites to enter into the program. Once the core of the PA program, former combat medics are now the exception in the PA course where more than 50% of the current candidates are prior service officers. Few new PAs now have experience as a medic. While the academic and clinical quality of the military PA has never been better, that key source of mentorship for a unit's medics, as well as the battlefield medical expertise these former medics brought to the combat arms commander, has significantly changed.

Training for military medics remained rudimentary until the 68W (the military occupational specialty (MOS) designation of the Army healthcare specialist) transition initiative in 2001 under the leadership of Army Surgeon General James Peake. LTG Peake, a decorated infantry officer who served in Vietnam before becoming a physician, recognized the critical nature of the medic's job in combat and pushed for the most significant enhancement in Army medic training in history. Army medics are now required to pass the civilian National Registry of Emergency Medical Technicians (EMT)-Basic examination, the entry-level civilian certification. "Whiskey training" then follows, where medics are taught the principles and techniques of Tactical Combat Casualty Care. These skills are then assessed at the end of their 4 months of training in a sophisticated 16-day field experience that incorporates mounted and dismounted patrolling, urban operations, and forward operating base and aid station operations. Initial entry medic training is now for the first time under the supervision of emergency medicine physicians with subspecialty training in EMS. This enables the latest prehospital medical innovations, training techniques, and research to be rapidly incorporated into medic training. Army medics are better trained in providing point-of-injury battlefield care today than at any time in history.

The enhanced level of initial entry training for combat medics represents a significant milestone, but more can be done. Civilian EMS providers follow a progressive professional pathway from EMT-Basic up to the EMT-Paramedic level. Providing paramedic-level education to Army medics would enhance their

lifesaving skills and could remedy an anomaly among MOSs—medics are among rare MOSs that throughout their careers are required to demonstrate proficiency only in their basic Skill Level 10. Most other MOSs require increasing levels of technical competency as rank increases. Introducing a clinical ladder or career pathway that allows for increasing technical competence could enhance promotion and retention and counter the high rate of 68W attrition.

The contemporary operational environment requires a broader skill set from medics than point-of-injury care and rapid evacuation. Conventional units and their medics are more dispersed in the battlespace and are in close contact with civilian populations. This presents unique challenges formerly encountered only by special operations medics. Such challenges include providing sick call in remote and isolated locations without a PA, caring for civilians which may include children and the elderly, prolonged care of the wounded when evacuation is delayed, and even veterinary and dental care. Conventional medics are only partially trained for these mission requirements.

Civilian helicopter EMS has advanced tremendously since its origins on the battlefields of Vietnam. It has now evolved into the most sophisticated mobile prehospital care platforms in the nation and serves virtually all Americans. In contrast, the inflight medical care during military helicopter medical evacuation (MEDEVAC) has remained relatively unchanged.¹⁰ The excellence of civilian air EMS provides valuable lessons for military aeromedical evacuation systems, including flight medic training and skill level, equipment sets, medical direction, quality assurance, and the development of intratheater critical care transport capability. This latter capability would solve a major challenge in the current wars in Iraq and Afghanistan as doctrine does not support the intratheater critical care transport of patients following emergency surgery at the forward surgical team (FST). In an effort to fill the gap, deployed medical leaders are pressing into service nurses (from the combat support hospital or FST) with variable levels of critical care and flight training to perform the transports. One of the most important lessons learned from civilian EMS is the value added from medical direction. Civilian helicopter transport systems have intense oversight from physicians with specific training in prehospital and en route critical care. Raising Army MEDEVAC standards to this level will likely require

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supplementing the local flight surgeon with an emergency physician.

A WAY AHEAD

Any improvement in battlefield care must first start with physicians within the AMEDD. Providing care in the troop medical clinic or the hospital ward are important and worthy missions for the military physician. But, of course, it is not the same as caring for casualties at the point of injury, running a battalion aid station during major combat operations, or transporting critically injured patients in a MEDEVAC helicopter. There have been several proposals over the years to define the “board-certified” military physician, but to date the precise skill set, training, and certification requirements for optimal battlefield practice have not been defined. The military should seek to develop physicians who specialize in prehospital and operational care. The closest civilian approximation is the emergency medicine specialist with subspecialty training in emergency medical services. This field of medicine requires unique training and a large body of specialized research centering on care outside the hospital. Training in EMS develops specialists who use a systems approach to improve prehospital care. While it would be difficult to place EMS-trained emergency physicians in every operational role, the EMS and military unique skills for providers operating in Role I should be defined and appropriately trained. The AMEDD should seek to systematically develop clinical *experts* in the practice of prehospital battlefield medicine.

The combat medic’s skill set should be broadened to incorporate the challenges of the contemporary operating environment. While it would be impossible to make every entry-level 68W into a special forces medic, a career pathway that increases technical competency as rank increases is a realistic goal. Entry-level medics (grades E-1 thru E-4) should be focused on Tactical Combat Casualty Care principles and point-of-wounding care, the current focus of the 68W initial entry training. Midlevel medics (E-4 thru E-6) should have a more advanced skill set, including the ability to perform remote sick call, more advanced trauma skills, and increased preventive medicine and camp hygiene skills. This medic should be able to deploy with and provide care for up to a company-sized element in a remote outpost with minimal support. Senior medics (E-6 thru E-8) would be responsible for battalion aid

station operations and should be able to assist the physicians and PAs during sick-call and mass casualty operations. These medics would also serve as the instructors at the AMEDD Center and School and medical simulation training centers, as well as serve as the “Master Medic” trainer at the brigade and division level. Senior medics should be trained at the civilian EMT-Paramedic level.

A clear professional path based on externally validated standards such as the National Registry of Emergency Medical Technicians certification examinations would ensure well-qualified and technically competent noncommissioned officers (NCOs) reached the higher ranks. Additional training at the paramedic level would also give midcareer NCOs the college credits needed to apply for AMEDD commissioning programs to become physicians, PAs, nurses, physical therapists, etc, bringing their invaluable combat and deployment experience into the AMEDD as commissioned healthcare providers.

With increased levels of training for all providers in Role I, sustainment training capabilities will have to become more robust. Current 68W sustainment is centered on recertification on Skill Level 10 MOS tasks. Sustainment should be standardized across different unit types and across the medical simulation training centers (MSTCs), available on every major division-sized post. These MSTCs could serve as the “medical range” for their respective posts, offering a large menu of training for Role I providers. The centers should be uniformly staffed and funded to conduct high quality training for tenant units.

Importantly, oversight of prehospital care should have coordination and visibility at the highest levels of the AMEDD. Among the many agencies sharing responsibility for prehospital care are the following:

- The Department of Combat Medic Training conducts initial entry training.
- The Department of Combat and Doctrine Development develops equipment and doctrine.
- Army EMS track certification currency.
- The Center for Pre-Deployment Medicine conducts training for deploying medics.
- The US Army Institute of Surgical Research conducts the battlefield care research.

Key Steps to Improving Battlefield Care

- ◆ Systematically train and develop clinical experts in prehospital battlefield care.
- ◆ Create a clinical ladder for the 68W MOS by providing increased training and certification as rank increases.
- ◆ Train flight medics to the civilian flight paramedic standard.
- ◆ Upgrade the medical simulation training centers to serve as the medical range for every division-sized post.
- ◆ Establish a high level battlefield care directorate or command staffed with personnel possessing appropriate and relevant clinical expertise.

- The Army Training and Doctrine Command integrates and develops medical training requirements for nonmedics.
- The Forces Command develops requirements for deploying units.
- The theater surgeon synchronizes requirements in theater.
- Unit medical officers execute battlefield care.
- Finally, the line commanders are the ultimate end-users of battlefield medical care.

Unified oversight could integrate these agencies and reap the benefit of improved synchrony and force responsiveness.

It is interesting to note that similar models already exist for synchronizing requirements, conducting strategic planning, integrating medical research, advocating for resources, directing process improvements, and developing training standards: veterinary care, dental care, public health, and warrior transition care. Each holds a place as a major subordinate command of the AMEDD.

CONCLUSION

The vast majority of Soldiers who die do so on the battlefield before reaching a physician. For combat casualty survival to improve further, the AMEDD must extend the investment made in FSTs, combat support hospitals, and fixed military treatment facilities to the prehospital and Role I setting. By taking advantage of a systems approach, casualty survival can be improved in far-forward areas of combat.

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Sharpening the Edge: Paramedic Training for Flight Medics



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BACKGROUND

Military physicians have long recognized that rapid evacuation from the battlefield decreases suffering and prevents death. Air medical evacuation (MEDEVAC) of seriously ill and injured patients during military operations was pioneered in the United States by the US Army. The first use of an aircraft to evacuate US Soldiers was in 1926 when the US Army Air Corps transported them from Nicaragua to Panama.¹

Helicopter evacuation came to the fore during the Korea War. Although the platforms were crude and no medical care was given during transport, more than 22,000 casualties were evacuated by that method.² Helicopter MEDEVAC would undergo significant expansion and growth during the Vietnam era. During this period, dedicated MEDEVAC helicopters were deployed en masse to Vietnam. The Bell UH-1 was large enough to carry several patients and a combat medic who could provide care en route to the hospital. This rapid evacuation to surgical care was one of the principal reasons for the significant reduction in battlefield mortality during the Vietnam War compared to other wars of the 20th century.

In 1966, with the Vietnam War at its peak, the National Academy of Sciences published a landmark paper entitled *Accidental Death and Disability: The Neglected Disease of Modern Society*, more commonly known as “the White Paper.”³ Researchers who prepared this paper noted that Soldiers injured on the battlefields of Vietnam and Korea received better medical care than residents of the United States injured on its highways. The White Paper led to the passage of the National Highway Safety Act⁴ and prompted Congress to pour millions of dollars into the development of our modern emergency medical services (EMS) systems.

Coincident with the development of modern civilian EMS systems were the end of the Vietnam War and

the demobilization of the physicians, nurses, and medics who served there. Many of these returning medical providers helped develop our current EMS systems based on their wartime experiences.

The first Emergency Medical Technician–Paramedic (EMT-P) programs were established in the late 1960s, and today EMT-Ps are operating in every state. In the early 1970s, the US military began to use its MEDEVAC helicopters based on wartime experience to transport civilians in the United States under the Military Assistance to Safety and Traffic program. Prehospital care and the development of civilian helicopter EMS systems underwent significant growth after the end of the Vietnam conflict. The civilian model evolved to become patient-centric, focusing on care delivered en route and training providers to a high level of care in the unique environment of the helicopter. The US Army’s model focuses on the platform, with greater emphasis given to aircraft performance and operations. En route care in the Army is generally provided by a single combat medic, a model rooted in the Vietnam War. A comparison of civilian and military helicopter EMS systems (Table 1) provides ample basis for healthy discussions on ways to improve Army medical evacuation care.

As a result of progressive development, civilian EMS providers have evolved into North America’s most sophisticated system of en route care. Air EMS has become the gold standard in managing and transporting severely ill or injured patients from the scene of injury or between medical facilities. To achieve this level of excellence, civilian aircraft are generally staffed by a pair of highly trained flight paramedics or comparably trained flight nurses.

CURRENT OPERATIONAL ENVIRONMENT

The Army currently staffs MEDEVAC helicopters with a single EMT-Basic (EMT-B). There are several reasons for this approach to staffing, including training

Table 1. Comparison between civilian and military emergency medical services systems.

Requirements	Army Flight Medic	Civilian Flight Paramedic (% programs that require)
EMT level	EMT-Basic (MOS requirement)	EMT paramedic (100%)
Experience	1 year as MOS 68W (EMT-B)	3 yr lead paramedic busy ALS system (70%); 5 yr (30%)
Certification/licensure	EMT-B	State or nationally registered EMT paramedic
Flight medic course	Currently not required	Not applicable
Training hours	No hour requirement for mission task 2120	New hire: 60 hr in classroom (75%)
Clinical hours	None	New hire: 40 hr of clinical rotations (75%)
Preceptor field hours	No hour requirement; Task 2120 will be evaluated by flight or standards Instructor until completed proficiently	New hire: 120 hr Preceptor Ride-Outs (50%) – based on type of aircraft flown and whether ride-outs can be done
Critical care training	Not required; JECC is available but not widely used by FM due to unit cost.	Program-specific requirement (80%)
RSI competency	Task not in flight medic's scope of practice	Required (100%)
ACLS	Required for flight medic course only	Required (100%)
ITLS/PHTLS	ITLS required for flight medic course only; PHTLS required by medic transition (once); no sustainment requirement	Required (100%)
PEPP/PALS	PEPP required for flight medic course only	Required (100%)
Documentation	No standard; often absent from medical record	Legal requirement in all states; used for PI, remediation, workload
Medical direction	Unit-based flight surgeon (usually a primary care specialty) is responsible for oversight. Most often has little trauma or EMS experience. No formalized interaction with flight medics. No standard PI process. No online medical control	Virtually all state medical practice acts require an emergency medical director with training in emergency medical/trauma or at least “extensive experience directing EMS.” Mandatory for ALS services; most systems use offline direction (retrospective PI review and remediation, continuing education, credentialing) and online direction (complex procedures, field declaration of death, protocol deviations, direct observation of EMT-Ps for validation)
Standard protocols	No standard US Army treatment protocols; unit-based	Required (100%)
Continuing medical education	TC 8-800 MEDIC (annual requirement focused on Level 10 MOS tasks)	Required (National Registry = 80 hr every 2 yrs)
Chart review/PI/QA	No standard	Required (100%)
GLOSSARY		
ACLS – advanced cardiac life support	FMC – flight medic course	PHTLS – prehospital trauma life support
ALS – advanced life support	ITLS – international trauma life support	PI – process improvement
APART – annual proficiency and readiness test	JECC – joint enroute care course	(%) = percentage of civilian programs who require
EMS – emergency medical services	MODS – medical operational data system	RL – readiness level (TC 1-210)
EMT – emergency medical technician	MOS – military occupational specialty	QA – quality Assurance
EMT-P – emergency medical technician-paramedic	PALS – pediatric advanced life support	RSI – rapid sequence intubation
FM – flight medic	PEPP – pediatric prehospital providers	

constraints, cost, and the origins of modern medical evacuation doctrine—a Cold War model that anticipated large-scale combined arms battles where rapidly “clearing the battlefield” was paramount and an austere level of care was necessarily assumed.⁵

The operational environment of Iraq and Afghanistan have challenged the traditional staffing model of one EMT-B medic on several fronts: *a*) transport of unprecedented numbers of civilians, including pediatric, geriatric, obstetric, and medical cases; *b*) transport of

postoperative critical care patients (levels II to III or level III to III); and *c*) transport across large geographic areas requiring prolonged inflight care. To illustrate these dramatic and unprecedented changes in helicopter medical evacuation, a synopsis of over 600 flights from one MEDEVAC unit’s recent experience in Operation Enduring Freedom is presented in Table 2.

Soldiers injured in remote, rugged areas (eg, most of Afghanistan and large swaths of Iraq) have been almost universally transported by MEDEVAC. Many

Sharpening the Edge: Paramedic Training for Flight Medics

Table 2. Synopsis of more than 600 MEDEVAC flights in one region during Operation Enduring Freedom.*

Types of Cases	Percentage of Cases	Description
Trauma	86	
Medical	14	Includes acute myocardial infarction, chronic obstructive pulmonary disease, stroke, toxic exposures, overdose, psychosis, seizures
Critical care	14	Intubation, vent management, chest tube insertion, advanced medications
EMT paramedic level	62	Includes critical care cases
Adult	94	Aged 18 to 68 years
Pediatric	6	Mostly trauma but also congenital heart conditions, toxic exposures, burns, sepsis, complicated child birth

*Data is from 9½ months of MEDEVAC operations by a 3 helicopter detachment in Afghanistan, 2008-2009. Source of data is internal military documents not normally accessible by the general public.

require advanced life support measures in order to survive even a brief flight to a forward surgical team (FST). Because FSTs are not able to hold postoperative patients for long periods, they in turn must evacuate critically ill postoperative cases following resuscitative surgery. These patients are likely to be sedated, intubated, on a ventilator, and are often receiving multiple medication drips and blood products. The knowledge and skills required to care for these cases unequivocally requires a paramedic or nurse with critical care training and experience.

The high-intensity needs of many postoperative casualties do not match the current level of training of flight medics. To fill the gap, deployed medical units (eg, FST) are, on a case-by-case basis, pressing nurses or other highly-trained providers into provisional flight service. While this expedient measure satisfies the immediate needs of the patient, it has consequences including temporarily depriving the thinly-staffed FST of a key provider. In some cases, pressing mission needs all but preclude the FST from sending a nurse, and a wrenching decision regarding patient transport ensues.

The case for more advanced training for flight medics is steadily growing. More than 40 combat-deployed unit after-action reports have identified Army flight medic training and skill level as a key issue and recommended paramedic level training as a solution. Typical examples of comments concerning flight medic capabilities received by the Army Medical

Department (AMEDD) Lessons Learned Center are presented in the Appendix.

As evidence mounts that improved patient outcomes are linked to better provider training, the Theater Trauma Consultants responded with a Clinical Practice Guideline (CPG) entitled “Intratheater Transfer and Transport of Level II and III Critical Care Trauma Patients.”⁶ The CPG states, “Polytrauma patients require a higher level of care than normally provided by MEDEVAC units.”^{6(p1)} The CPG further recommends that a nurse or physician trained in critical care accompany these patients. As a result of the Theater Trauma Consultants’ input, 18 critical care nurses have recently been deployed to Afghanistan to supplement the flight medics in theater. Other elements of the system have responded in similar fashion. In March 2010, the US Army School of Aviation Medicine recommended changes to flight medic training, including additional skills, tasks, and training to close the capability gap. Implementation of the recommendations, however, requires a significant reprioritization of resources and action is pending.

In summary, 21st century conflicts will demand flight medics who can operate across the full spectrum of operations. Future combat operations are envisioned to be increasingly expeditionary in an “era of persistent conflict.” Forward and theater medical assets will be smaller and more dispersed. Forces will likely operate across large geographic areas requiring prolonged and advanced care by the flight medic. We will likely continue to operate among civilian populations, both local nationals and contractors, necessitating transport of pediatric, geriatric, and medical cases typical of air ambulance operations in the United States. Furthermore, consequence management operations and defense support to civil authorities in the United States related to disasters or large-scale terrorism will require flight medics with the same skills as their civilian counterparts in order to be fully integrated in the medical response plan.

PROPOSED SOLUTION

Meeting the unprecedeted challenges of medical evacuation requires steps that are at once bold and yet familiar: training all US Army flight medics to flight paramedic competency and certification as described in the 2009 International Association of Flight Paramedics Position Statement (Table 3). The training is

bold because of the intensity and the skill level that a select group of combat medics will achieve. It is familiar because the AMEDD and the Army has decades of experience in training small groups of motivated enlisted Soldiers in highly technical and specialized medical fields, such as licensed practical nurses, cardiovascular technicians, and special forces medical sergeants.

It is posited that this training could be rapidly implemented under realistic resource ceilings. Training could be conducted in 3 phases totaling approximately 32 weeks. Costs are estimated at \$10,000 per flight medic, in addition to permanent change of station costs for initial flight paramedic training.

Phase I: Military Flight Medic Training

Program Length: Currently 4 weeks.

Location: Fort Rucker, Alabama.

Cost: Temporary duty at Fort Rucker and associated course costs.

Prerequisites: 68W with at least 3 years of experience, preferably at least one combat deployment, current BLS/EMT-B, valid flight physical, meets height, weight, and Army Physical Fitness standards.

Description: Program would incorporate elements of current Flight Medic course focusing on physical and mental fitness, validation of combat medic skills, aircraft and flight operations, and Readiness Level (RL) progression. This would serve as the selection and assessment phase to ensure that candidates are physically and mentally capable to perform the duties of a flight medic. At the end of this phase, candidates who successfully completed the course would return to their units and permanent change of station to Fort Sam Houston for phase II.

Phase II: EMT-Paramedic

Program Length: 1000 hours (20 weeks)

Location: University of Texas Health Science Center, San Antonio, TX (UTHSC-SA).

Costs: ≈\$6,000 per student for course costs. Permanent change of station move to Fort Sam Houston for Phases II and III.

Prerequisites: Completion of Phase I.

Description: Program would model the existing San Antonio Fire Department Paramedic training course, a

fully accredited EMT-P program. The current UTHSC-SA program can accommodate 20 to 30 US Army flight paramedic candidates per class, up to 60 per year. At the end of the course, students would achieve the National Registry of EMT-Paramedic Certification. On-course completion students would be eligible for 33+ semester hours of college credit. A historical precedent with UTHSC-SA and the US Special Operations Command Paramedic program exists where Special Forces medics trained as EMT-Ps in San Antonio. Existing memoranda of agreement could be modified to accommodate US Army flight paramedic candidates.

Phase III: Critical Care Flight Paramedic

Program Length: 524 hours (120 classroom, 284 clinical, 120 field training exercise) (8 weeks)

Location: Brooke Army Medical Center (BAMC), University of Texas Health Science Center-San Antonio, San Antonio Air Life.

Prerequisites: Completion of Phase I and II and National Registry of EMT-paramedic certification.

Costs: Would be based on cooperative agreements with UTSAHSC, BAMC, and Air Life. Clinical rotations would be conducted at BAMC, an existing military facility with little associated costs.

Description: Students would learn and apply principles of critical care in the classroom, laboratory, clinical, and field settings. Student rotations will include operating room/anesthesia service; medical, surgical, cardiac, and pediatric intensive care units; the Institute of Surgical Research burn unit; and San Antonio Air Life. Clinical and didactic rotations will be followed by a 120-hour continuous field training exercise at Camp Bullis, Texas, that is reflective of the current contemporary operational environment.

END STATE

Following this recommended training pathway, the US Army flight paramedic will:

- Be prepared to take the Flight Paramedic Certification Exam.
- Be trained to entry-level civilian flight paramedic proficiency/competency.
- Be able to provide competent en route care to most critically ill or injured patients from the point of injury or between medical treatment facilities.

Sharpening the Edge: Paramedic Training for Flight Medics

Table 3. 2009 International Association of Flight Paramedics Position Statement.⁷

Area	Standards
1. Experience	Minimum 3 years of experience as a combat medic
2. Education	<ul style="list-style-type: none"> a. Primary: Successful completion of the paramedic National Standard Curriculum or equivalent. b. Secondary: Successful completion of a critical care education program that meets or exceeds the educational objectives of this position statement, including didactic sessions, practical sessions, skill proficiency demonstration, and clinical rotations c. Tertiary: Continuing mentored didactic education, skill maintenance, and clinical opportunities that maintain the educational objectives of this position statement
3. Certifications	<ul style="list-style-type: none"> a. Advanced Cardiac Life Support b. Adult and Pediatric International Trauma Life Support / Prehospital Trauma Life Support / Advanced Trauma Life Support c. Pediatric Advanced Life Support / Advanced Pediatric Life Support d. Neonatal Resuscitation Program e. Or an equivalent education in each of the aforementioned areas
4. Knowledge	<ul style="list-style-type: none"> a. Assessment of the critically ill or injured patient b. Advanced adult and pediatric airway management including, but not limited to: <ul style="list-style-type: none"> i. Rapid sequence induction (RSI) intubation ii. Alternative and rescue airways iii. Surgical cricothyroidotomy iv. Continuous waveform capnography to monitor end tidal carbon dioxide (ETCO₂) c. Mechanical and noninvasive ventilation theory, troubleshooting, and competence d. Chest tube thoracostomy management and insertion (if applicable) e. Obtain and maintain peripheral venous, central venous (if applicable), and/or intraosseous access f. Administration of blood and blood products g. Electrocardiogram (ECG) monitoring and 12 lead ECG interpretation h. Defibrillation, cardioversion, and transcutaneous and transvenous pacing monitoring, maintenance, and treatment i. Circulatory management and support including invasive hemodynamic monitoring and intra-aortic balloon pump (IABP) management (theory, transport considerations, troubleshooting, and operations, if applicable) j. Intracranial pressure monitoring and management k. Pharmacology included in the National Standard Curriculum augmented by knowledge of analgesics, antibiotics, antidysrhythmics, antiepileptics, paralytics, sedatives, and vasoactive medications l. Laboratory value interpretation including arterial blood gas analysis m. Targeted radiology study interpretation
5. Patient management	<ul style="list-style-type: none"> a. Acute respiratory emergencies b. Cardiovascular emergencies c. Hypertensive emergencies d. Shock and multiple organ system failure e. Infectious diseases f. Neurological emergencies including stroke and intracranial hemorrhage g. Trauma h. Spinal cord injury i. Burn j. Trauma in pregnancy k. Pediatric trauma l. Critical pediatric emergencies m. Obstetrical emergencies n. Neonatal emergencies (if applicable) o. Environmental emergencies p. Poisoning / toxic exposure / hazardous material awareness q. Bioterrorism
6. Transport medicine	<ul style="list-style-type: none"> a. Safety <ul style="list-style-type: none"> i. Vehicle operations and emergency procedures ii. Critical care transport equipment iii. Patient / family factors iv. Human factors (including but not limited to air medical resource management (AMRM) or equivalent) b. Evaluation of appropriateness for transport based on required level of care c. Transport logistics d. Critical care transport equipment (ventilator, IABP, neonatal isolette, etc.) e. Patient packaging for safety and accessibility f. Radio and communication technology g. Transport physiology h. Interaction and communication with medical oversight i. Medical provider communication / transfer of care j. Documentation
7. Quality management	Understanding principles and best practice
8. Certification examination	Successful completion of a critical care paramedic certification examination. Along with the FP-C®, the IAFFP recognizes the Critical Care Paramedic Certification Examination (CCP-C®) as a valid certification examination for the critical care paramedic.

- Provide Soldiers wounded on the battlefield with the same level of care as a civilian evacuated by helicopter receives in the United States.

TRANSITION AND SUSTAINMENT

Although 2 classes of 25 to 30 to medics per year would meet the requirements of the current conflict, it would be insufficient over time to generate sufficient numbers of flight paramedics to fill every air ambulance unit in all 3 components as authorizations increase from 645 total flight medics currently to a projected end state of 1173 flight medics in the year 2017.

Since the proposed course is conducted in different phases, the modular nature of the proposed course would make Phase II, the paramedic phase, easily exportable to other accredited paramedic programs near a flight medic's current post. The 101st Airborne Division sent all of its flight medics to civilian paramedic training near Fort Campbell prior to their most recent deployment to Operation Enduring Freedom. The 82nd Airborne Division is also implementing a paramedic program with an additional critical care course for their flight medics. It is likely that a large number of flight medics, especially in the Army Reserve and the National Guard, are already qualified as EMT paramedics. A survey to determine the exact numbers should be conducted since this qualification is not currently tracked in Army personnel systems.

Phase III, the critical care phase, could be reproduced at other medical centers with an adequate volume of critical care patients and at which a cooperative

arrangement could be established with a supporting civilian air ambulance service.

The proposed modular design would facilitate "off the street" civilian paramedics and flight paramedics enlisting directly into the Army flight paramedic program. Flight medic trainees would first attend basic combat training, the battlefield portion of MOS 68W initial entry training, and fast-track directly to the appropriate phases of training required to meet the US Army flight paramedic standard.

To better illuminate resource issues, it is useful to examine the cost of training a Special Forces Medical Sergeant (MOS 18D), another highly-trained enlisted medic. Cost for class VIII supplies and temporary duty alone during the medical phase of training of an 18D are approximately \$45,000 per individual trained. These medics treat a relatively small number of patients entering the evacuation system. The cost to train a critical care flight medic will be about one-third of this amount, yet flight medics touch 95% of the patients evacuated in Operation Enduring Freedom.

One of the reasons cited for leaving the Army following the initial enlistment by 68Ws is the lack of additional training opportunities and lack of a career pathway that includes additional certifications. A flight paramedic program would provide a career ladder for 68Ws. While there will likely be attrition just as there is in the MOS 18D course, a system of bonuses and selection would mitigate this. The current University of Texas Health Science Center-San Antonio paramedic training program has a greater than 88% pass rate.

Sustainment training for an advanced flight medic (Table 4) would naturally be more intensive than the current 68W flight medic model. However, in many respects sustainment can be easier for military paramedics given our access to military treatment facilities for clinical time and our medical simulation training centers. Sustainment is the other side of the advanced flight medic coin. Without a well thought-out sustainment plan, the benefits of rigorous initial training would wane over time. Flight medic competency and sustainment should be tracked on the Unit Status Report, as is aircrew readiness.

Proficiency pay and enlistment bonuses will be key features in attracting and sustaining highly qualified

Table 4. Process for sustaining flight paramedic certification.

Frequency	Activity
Monthly	Four intubations on simulators, cadavers, live patients, or animal models
	Four training scenarios on simulators, live patients, or animal models. One each: trauma, pediatric, medical, critical care
Every 6 months	One-week anesthesia rotation with a minimum of 5 live intubations
Every 2 years	Recertification of ACLS, PALS, PHTLS, AMLS, or equivalent courses
	Two-week Medical Proficiency Training rotations in an intensive care unit or with a busy civilian EMS/Air Ambulance service
Every 4 years	Four-week trauma center rotation
	Total of 100 Continuing Education units required for FP-C recertification in addition to 2-day FP-C recertification course
Predeployment	One-week FTX (same as final FTX in Phase III)

flight paramedics. Proficiency pay should be linked to passing the rigorous Flight Paramedic Certification Examination and maintaining this certification through a rigorous sustainment process (Table 4). Proficiency pay should bring the US Army flight paramedic's salary to the civilian flight paramedic entry-level pay of approximately \$45,000 per year. Proficiency and bonus pay will be key features in attracting high-caliber enlisted Soldiers into this career pathway, and retaining them.

The idea to increase the training of Army flight medics to the civilian flight paramedic level may superficially appear to be a radical departure from current practice. In fact, the idea that has been around for more than a quarter century, beginning with the Division 86 concept and advocated in several other studies examining MEDEVAC.⁸⁻¹⁰ A detailed review article made a comprehensive case for paramedic trained flight medics in 1997.¹¹

Counterarguments to the concept of paramedic flight training must be considered. These include: *a*) costs that exceed value, *b*) difficulties in achieving training success (and consequent classroom attrition), *c*) combat units unlikely to embrace the change or the burden of sustainment, *d*) the sustainment tail will be expensive, *e*) the National Guard and Reserve will be challenged to meet the increased time commitment of training, and *f*) competition from civilian employers will increase as they seek to hire away the now highly-trained flight medics. While acknowledging these possibilities, it is instructive to consider the history of the then 91W (now 68W) combat medic program. During its inception, each of these counterarguments were postulated (some quite vigorously), but ultimately all were refuted. The resounding success of the 68W program stands as testimony to the ability of the AMEDD to achieve deep and lasting success in enlisted medic training.

CONCLUSION

The US Army pioneered the concept of helicopter evacuation, and justifiably stands proud as the father of modern air EMS. In turn, civilian helicopter EMS has now come full circle since the Vietnam War and the publication of the White Paper³ on trauma in the 1960s. It is now the most sophisticated delivery platform for prehospital care in the United States. To

continue the cycle, the US Army stands poised to combine outstanding MEDEVAC aircraft capabilities with the advanced training of flight paramedics.¹¹ The ultimate goal is improved care for battlefield casualties and a more responsive and flexible medical evacuation system. Flight paramedic training is an important step in keeping combat casualty care on the cutting edge.

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APPENDIX

Sample of comments from units deployed to Operations Iraqi Freedom and Enduring Freedom regarding flight medic capabilities and qualifications received by AMEDD Lessons Learned (<http://lessonslearned.amedd.army.mil>).

Observation: Flight medic training

Discussion: Like civilian EMS, many of the MEDEVAC missions involve routine patient transfers. Even the majority of point-of-injury patients require mainly basic life support skills, with oxygen therapy and intravenous infusions accounting for the majority of medical interventions. About 5% of these patients, however, are critically ill or are injured patients who present with unstable airways or hemodynamics requiring advanced airway management and other lifesaving interventions. This population of patients is precisely where skills and training need to be focused, they are the patients most likely to require and benefit from aggressive advanced prehospital care. Reviewing these cases made it clear that there were many cases in which the current flight medic training program falls short. Additionally, there was a sizable subset of cardiac/chest pain patients for which the medic was the only medical attendant. The current training program does not adequately prepare flight medics for treating cardiac patients, who were frequently transferred without appropriate treatment or safeguards. In the 1159th and 54th Medical Companies, many of the patients were critical-care interfacility transfers involving patients who were chemically paralyzed, sedated, intubated, on a ventilator with ongoing drug administration, chest tubes, and intensive hemodynamic monitoring. The 1159th Air Ambulance was a Guard unit in which about a third of their medics are civilian EMT-Ps, including 2 medics who were Critical Care EMT-Ps. Fortunately, this unit performed a large number of the critical-care transfers.

While a medical attendant is often provided from the combat support hospital or forward surgical team, in the early stages of this conflict that was not always possible nor would it be possible in the expeditionary phase of most future conflicts.

Lesson Learned: The current flight medic training program is not sufficient as a standalone program to provide the critical-care aeromedical skills necessary to treat the most severely injured patients experienced during this operation.

Authors' Recommendation: The flight medic needs solid MOS 91W skills supplemented by the skills of the Advanced Cardiac Life Support (ACLS) and Critical Care Air Transport Teams, coupled with continuous clinical practice. Excellent airway management and endotracheal intubation skills are essential. Although a patchwork system of courses can be created to try to meet this need (and it is likely to be the short-term fix), what is really needed is an EMT-P level certification that includes the necessary clinical experience in critical care and advanced level procedures, similar to the Special Operations Combat Medic program. The vast majority of flight programs in civilian air ambulance programs include a flight nurse and an EMT-P as the medical attendants. The key is clinical experience in addition to the enhanced critical care didactics. Completing an ACLS course does not mean that you adequately understand cardiac pharmacology or arrhythmia recognition sufficiently to provide advanced cardiac care independently. No civilian air or ground ambulance crew could provide that level of treatment in the United States without completing a paramedic course that included extensive didactic and clinical training in the relevant conditions and treatment. The curriculum from the Joint Enroute Critical Care course is inadequate for 91W medics, as is the civilian Critical Care EMT-P course, since they were designed to provide an already experienced field EMT-P with additional critical care air transport skills, not to turn an EMT-B provider into a Critical Care Transfer Paramedic! It is dangerous to train a medic to maintain deep sedation and paralysis during transfer of a ventilator patient unless he has excellent intubation skills, chest decompression skills, ventilator management skills, and the clinical experience to treat the potential complications. Flight medics should accordingly be maintained in the career field as long as they desire to do so by stabilizing assignments and allowing for promotion through E-7 as flight paramedics, because of the cost of training and perishable skills. Alternatively, flight paramedic positions could be made warrant officers, much as with other technical fields, to retain the flight medical skills and experience where they are needed the most.

Deployment/Operation: Operation Iraqi Freedom

From the 3/10th IBCT Operation Enduring Freedom deployment: Flight medics require training to reach the paramedic skill level in order to provide the en route care necessary for critically injured casualties evacuated from the forward surgical team (FST) after life-sustaining surgery to Role III facilities. The Army National Guard flight medics are paramedic-qualified and better trained to care for potential issues when evacuating patients from the FST after surgery than are active-duty flight medics who are trained to the minimum qualification: EMT-B; BTLS; ACLS; PHTLS; and PAL standards. Flight medics also need more training on ventilation and transporting sedated patients. Flight medic training was identified by the unit as a top issue.

Sharpening the Edge: Paramedic Training for Flight Medics

APPENDIX (CONTINUED)

Observation: Need for increased medical training for flight medics.

Discussion: The war on terrorism is a new kind of war fought with mostly Special Forces. Most of the Special Forces and medical facilities located in Afghanistan did not want to use our medics and paramedics because they were not trained by Special Operations Forces (SOF). At the request of the SOF, a doctor, physician-assistant, or SF medic would accompany patients, taking away that medical asset from the battlefield. The MOS 68W program is a good start to the 91 series in the Army, but it needs to be taken to a new level for flight medics.

Lesson Learned: SOF units are reluctant to trust EMT-B trained medical personnel.

Authors' Recommendation: In dispersed operations, MEDEVAC is always provided for more critical patients; whereas lower-priority patients are evacuated by ground. The current knowledge, skill set, and critical decision-making performed by current Army flight medics do not provide the breadth and depth of care our civilian counterparts have come to expect. Flight medics should be trained to the paramedic level to provide a higher level of care, so that other elements will be more confident in their abilities and the medic better prepared to handle an urgent MEDEVAC.

Deployment/Operation: Operation Enduring Freedom, Afghanistan.

From the 4/4th IBCT Operation Enduring Freedom deployment: Flight Medic Training. The unit noted that all the National Guard air ambulance company flight medics (68WF) had paramedic certification. As a result, the National Guard flight medics had superior skills to monitor and provide advance inflight care for critically injured patients when compared to the active-duty flight medics. Paramedic-qualified flight medics are able to intervene and handle potential issues that severely injured patients may experience. This issue has been noted in previous After Action Reports, and the AMEDD Center and School is evaluating the training requirements for the flight medics to determine whether all need to be trained to the paramedic level.

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